

REGISTRATION

86230-2

ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

EPA Receipt Date: MAR - 5 2010		EPA Reg. Number: 86230-E		
	Check List Item	Yes	No	N/A
1	Has the PRIA Fee been Paid ; is a copy of the check or Pay.gov receipt included in the Submission Package?	X		
2	Is an Application Form (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	X		
3	Is a Confidential Statement of Formula (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	X		
4	Is a Formulator's Exemption Statement (EPA Form 8570-27) Included in the Submission Package?	X		
5	Is a Certification with Respect to Citation of Data (EPA Form 8570-34) Included in the Submission Package?	X		
6	Is a Data Matrix (EPA Form 8570-35) Included in the Submission Package?	X		
7	Is a Label Included in the Submission Package?	X		
8	Are Data Included in the Submission Package?	X		
9	Is the Submission an Amendment?		X	

**Labeling Considerations from
EPA Meeting of 23 September 2010
LoradoChem Products**

Dear BA,

Thanks to you and Mr. Gebkin for a very productive meeting on September 23rd. Many points were made clear and others remained open. As we discussed, I have assembled the following list for which we seek your further guidance.

Efficacy & Richard

1. Use of the trademark "Vetrust" for the product

Question: EPA indicated that this trademark be reviewed by an internal board to determine its suitability.

- a. LoradoChem respectfully submits that the fanciful and distinctive VETRUST brand name is neither false nor misleading when used in connection with Loradochem's Fipronil, S-methoprene products. Specifically addressing the EPA's guidelines for brand name selection, VETRUST does not convey any false or misleading claims about the product's efficacy. Further, VETRUST does not state or imply any claims regarding the product's safety or superiority to other products. Neither does the VETRUST name make any false or misleading claims about the product's ingredients. Simply put, the VETRUST brand name does not convey any impressions or ideas about the product that would confuse or mislead the pet-owning public.
- b. Loradochem purposefully chose the VETRUST brand name because it does not communicate any specific claims about the Fipronil, S-methoprene products. In fact, the name VETRUST is an arbitrary and fanciful term that conveys only abstract messages. The prefix VET was selected to identify the category to consumers that the product is used for veterinary animal care, and the term TRUST is used to elicit a general feeling of confidence. Neither of these terms, whether they are considered separately or together, communicate specific material ideas about the product.
- c. Loradochem notes that the EPA has approved brand names that are much more suggestive of specific product attributes than the proposed VETRUST brand name. For instance, the EPA has approved the ADVANTAGE brand name, which communicates ideas about the product's superiority within the flea and tick pesticide industry. Additionally, Hartz has been permitted to market its flea and tick pesticide under the name HARTZ ULTRAGUARD, which projects ideas about the product's efficacy and superiority. Moreover, the EPA allows Sentry to market its flea and tick pesticide for cats under the PURRSCRIPTIONS brand name, which may convey to potential consumers that Sentry's product is available by prescription only or that it is prescription-strength. Velocera's comparatively vague and subtle VETRUST brand name should be granted approval as well.
- d. Finally, the Patent and Trademark Office ("PTO") reviewed the trademark application for the VETRUST mark (U.S. Serial No. 77/499,324) and did not find the mark to be descriptive or deceptively misdescriptive of Loradochem Fipronil, S-methoprene products. While we acknowledge that the PTO's findings are not binding on or dispositive of the EPA's analysis of brand names, it is significant that another regulating entity -- indeed, one well-suited to assessing the issue of whether a term describes product attributes -- did not raise

any descriptiveness objections to the VETRUST trademark application. Moreover, in the event that the VETRUST brand name unexpectedly creates any misimpressions among consumers (which we are confident will not be the case), the Federal Trade Commission and Loradochem's competitors would undoubtedly not hesitate to take action to prevent such confusion.

- e. Loradochem respectfully requests that the EPA approve its VETRUST brand name because it does not convey any false or misleading messages about Loradochem's Fipronil, S-methoprene products and is, therefore, in compliance with sections 12(a)(1)(E) and 2(q)(1)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and 40 C.F.R. Sections 156.10(b)(2) and 156.10(a)(5).

2. **Claims made about the active ingredient.**

Question: On the proposed cartons, we have a round, visible circle on the front panel which inside has the phrase, "Compare to Frontline (or Frontline Plus) same active ingredient(s)." On the back panel, we have a chart which again compares the products based on the described formulations, listing fipronil, s-methoprene (if applicable) and "Inert ingredients," the columns of which are based on our formulation and the ingredients statement from the front panel of the pioneer product. Concern was expressed that comparative statements may be unacceptable.

- a. We based our decision to follow this path based on the EPA Label Review Manual, Chapter 12: Labeling Claims, and specifically Section V. In Section V., EPA states that a registrant may make claims about the active ingredient and note that it is the same active ingredient as the one used in another particular brand, if certain conditions are met, and we believe we have met those conditions.
 - i. First, the statement can be anywhere on the label, but EPA prefers it to be in "close proximity" to the Ingredient Statement. Both appear on the front panel and in the lower third of the panel.
 - ii. The statement is not in an overly large font, as noted. It does not excessively stand out, and we do not feel that it causes greater attention than other Precautionary labeling text.
 - iii. We have followed the guidance concerning single active ingredient and multiple active ingredient products. The fipronil only products ask the consumer to compare to Frontline, while the fipronil and s-methoprene products ask the consumer to compare to Frontline Plus. In addition, as defined in the Label Review Manual, there is an, "Appropriate disclaimer(s) stating that the generic product is not manufactured or distributed by the maker or marketer of the brand-name product as well as the trademark of the brand may be cross reference(d) by use of a footnote." The disclaimer appears on the front panel to the left of the statement and below the ingredients statement. Attachment I shows the proposed use on the Vetrust carton and a similar treatment from the OTC human drug market, confirming that this practice is seen and understood by consumers.
 - iv. The table on the back panel is nothing more than a statement of fact, and certainly not false or misleading in any way. Again, it is giving the consumer information useful in comparing the generic and the pioneer products, showing the similarities in the ingredient statements of the respective products.

- b. For these reasons, we believe the statements made about the active ingredient(s) are consistent with the EPA Label Review Manual and should be found acceptable.

3. **Supporting information concerning the use of "Waterproof"**

Question: EPA questioned whether product specific data should be required for the LoradoChem formulations which contain fipronil.

- a. LoradoChem specifically developed the formulations submitted to EPA with two objectives. First, the formulations needed to be outside the existing patents of the pioneer concerning formulated products. Second, while not violating the patents, the LoradoChem formulations were still to meet the criteria of EPA to be "substantially similar." As shown by the confidential statements of formula for the four submitted products, the differences between the pioneer products and the LoradoChem products are minimal. The information LoradoChem used in making this determination was a deformation effort as well as review of the publically available information on the pioneer products that are approved there. Attachment II shows charts which compare the three formulations of interest, the

w/w). In analysis of the products, LoradoChem believes there is no reason to think that the small changes in the formulations would have any impact on the pioneer and the LoradoChem products concerning the ability to wash off in field use.

- b. These conclusions are supported by data from the pioneer. The pioneer has published a radiolabeled study using ^{14}C fipronil in a spot-on formulation, and demonstrating where the molecule persists on the dog and cat. The pioneer concludes that **fipronil** is present in the pilosebaceous units along the hair and that the persistence is due to the migration of **fipronil** by passive diffusion in the sebum covering the hairs and skin. Blood levels do not play a role, so there is no systemic activity involved. It is this reservoir effect that allows the **fipronil** to persist on the dog or cat for the extended time. This characteristic is related to the active ingredient and not the formulation. The pioneer attributes the lasting effects to the active ingredient, not the product formulations. (A copy of this material from the pioneer is included in Attachment III). It is this reservoir effect of **fipronil** active ingredient that prevents the **fipronil** from washing off the animal.
- c. Other authorities have recognized this characteristic of the fipronil, and not the formulation. In the veterinary text book, Small Animal Dermatology, by Muller & Kirk, the authors conclude concerning fipronil that, "Because the sebaceous glands replenish the drug lost at the skin's surface, water immersion or bathing is reported to have minimal impact on efficacy for at least 30 days."
- d. A physical-chemical characteristic of fipronil also plays a role. It is quite clear from the chemistry of the molecule that fipronil has very low water solubility. As such, the volume of water needed to dissolve any amount of fipronil is quite

Inert ingredient information may be entitled to confidential treatment

high on a comparative basis. This low water solubility makes the active ingredient, fipronil, less likely to be washed off the animal after water immersion or shampooing.

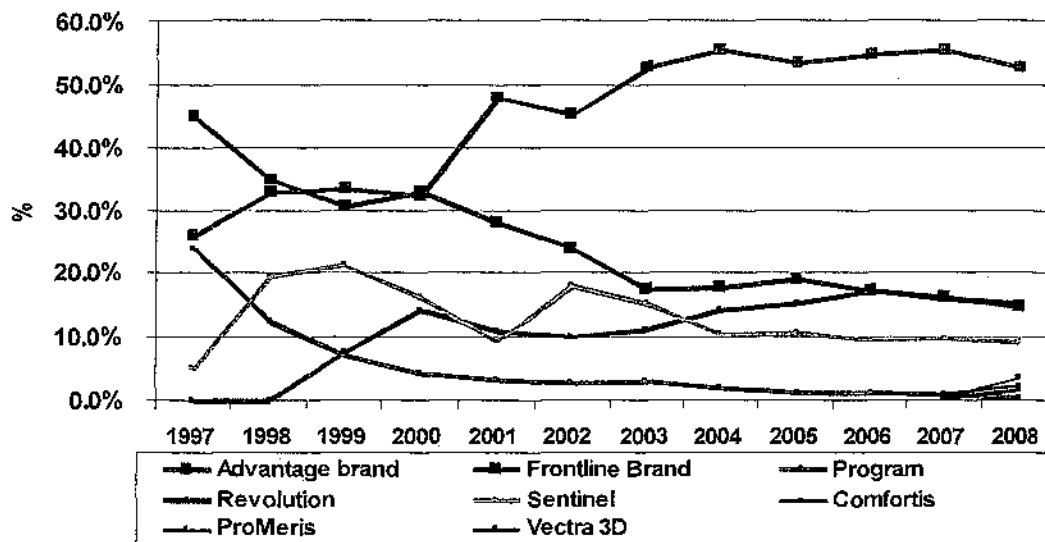
- e. For the above reasons, we believe that the labeling should carry the point “waterproof”, as the formulations are substantially similar and the data to support this is included in the pioneer’s application, and data compensation has been offered to the pioneer.

4. Use of the phrase, “#1 Veterinarian Recommended Active Ingredient(s)”

Question: EPA expressed concern about the use of this phrase on the front panel of the box.

- a. We based our decision to use this phrase relying on the EPA Label Review Manual, Chapter 12: Labeling Claims, and specifically Section VIII. Section VIII discusses any “unusual claims” concerning the efficacy of a product. As for any claim, EPA holds that a product will be misbranded under FIFRA if a statement is false or misleading. Such is not the case with this statement. Market data from the veterinary field clearly show that Frontline and Frontline Plus are today and have been for many years (since 2001) the largest selling products of all animal health products sold for dogs and cats. As such, fipronil and s-methoprene are the most widely recommended active ingredients recommended and sold by veterinarians in the United States and the world. As such, while the statement may or may not be a “claim” concerning the efficacy of the product, it is neither false nor misleading in the sense that it is a true statement and verifiable by publically available sales data.
- b. This is an accurate claim supported by market research and Merial’s own website. Fipronil has been the #1 Veterinarian recommended active ingredient on a dose basis since 2001, according to Market Dynamics Inc, the leading market research firm throughout the applicable period providing market share statistics for all veterinary products sold through animal health distribution channels

U.S. Vet Channel Flea & Tick Market Share 1997-2008, Doses



Source: Market Dynamics Inc.

Today, fipronil is approximately 50% of the doses in the Veterinarian channel at least two times its nearest competitor. On a dollar basis, it is close to three times with retail sales in the US exceeding \$1.2B.

- c. For these reasons, we believe the statement as presented should be suitable for use on the front panel of the carton.

Richard

5. Use of "Other" vs. "Inerts" in the Ingredient Statement

Question: EPA indicated that the current preference is to use "Other" to designate the proportion of the finished products that are non-active components instead of the previously used term, "Inerts." The pioneer is using "Inerts" in their labeling.

- a. LoradoChem will be offering a "me too" or generic version of the pioneer products, Frontline and Frontline Plus. When moving into the market as a generic version of an established product, it is important to show the pet-owning public that the products are essentially the same without confusion. For that reason, LoradoChem prefers to have an ingredient statement using the same term as the pioneer, who has been and is still using the term, "Inert" in their labeling. This was found to be the case based on the March 2010 label approved by EPA for Merial. On that label, the pioneer uses "Inert Ingredients" in their statement.
- b. When researching this issue using the Label Review Manual, Chapter 5: Ingredient Statement, it was learned in Section II that the EPA position is as follows. "PR Notice 97-6 recommends "OTHER INGREDIENT" instead of "INERT INGREDIENT", but either may be used." In order to maintain consistency with the pioneer ingredient statement, LoradoChem plan to use "INERT" as a descriptive term, switching to "OTHER" when the pioneer changes their labeling.

clp

6. Directions to Instruct the Consumer for Opening the Packaging

Question: Directions for this section of the labeling have been previously discussed with EPA to insure compatibility with the CRP aspects of the package from a Senior Test Panel standpoint. At the early stage of review, EPA and LoradoChem agreed to make the first instruction read, "Open the child resistant package according to the directions on the back of the child resistant package."

- a. After seeing the agreed upon direction in type set on a prototype carton, it seems to LoradoChem that the wording will be confusing to the pet-owning public, and we would like to explore alternative approaches that would be more clear.
- b. First, LoradoChem proposes to put a line of text that states, "How to Apply" above this area of the carton and the package insert.
- c. Second, LoradoChem proposes to add a drawing to the two drawings currently appearing above the written text. This drawing would depict cutting the single blister package, similar to the graphic on the blister package drawing. A copy of the proposed graphics are included here in Attachment IV and on the carton sample provided to EPA at the meeting.
- d. Third, LoradoChem proposes to use the language from the blister package as the first numbered point. So it would now read:
 - i. 1. TO OPEN PACKAGE: Cut across the top as shown. Peel down foil completely before removing pipette.
 - ii. 2. Snap the tip of the applicator away from you as shown.
 - iii. 3. Part the dog's (or cat's) hair and place the tip of the applicator to the skin level behind the neck and between the shoulders. Ensure that the entire application of Vetrust for dogs (or cats) is contained in a single

spot on the dog's (or cat's) skin. Be sure to squeeze the applicator thoroughly so that the entire contents are applied.

- e. Fourth, as requested, LoradoChem proposes to change the Storage statement to read, "Store unused applicators in the original unopened child-resistant container and outer box only, out of reach of children and animals."

7. **Use of "Applicators" vs. "Applicator Pipettes" on the labeling**

Question: EPA requested LoradoChem describe the replacement of "Applicator Pipette" with "Applicator" on the labeling components.

- a. LoradoChem has assessed the use of the term "Applicator Pipette" in the product labeling. As demonstrated in the meeting, the sample carton is very crowded when printed in its entirety. As a means to make the text less crowded and more clear to the pet-owning public, LoradoChem is seeking ways to remove unessential words from the text. With less text, the essential material is easier to read and should be more clear. One way to improve this situation would be to remove the redundant word, "pipette" when it follows "applicator." We believe that "Applicator" is a more understandable term for the consumer, as pipette is more scientific in nature. The word "pipette" precedes "applicator" XX times in the labeling, adding no informational value and potentially causing confusion or clutter.
- b. LoradoChem does understand that the exact words used in the Senior Panel Testing are important. In that testing, the phrasing on the blister package (the Child Resistant Element of the packaging) stated, "TO OPEN PACKAGE: Cut across the top as shown. Peel down foil completely before removing pipette," and that if this phrase were to be placed on the carton or the package insert, this exact wording should be used. However, we believe in the interests of Consumer understanding, that in other instances, "applicator" is more understandable.
- c. LoradoChem could also combine both approaches. For example, on the front cover of the carton in the upper right corner, the drawing could show the number of applicators in the box of the appropriate color and then call them "Applicator Pipettes" to keep that terminology on the front. On the back panel of the carton, which has the most text, we would propose to use "Applicator."
- d. Any changes made to the carton would be followed through on the package insert as well.

8. **Use of the phrase "For animal use only" on the bottom flap of the carton**

Question: EPA stated that they would prefer that the phrase, "For animal use only" be more specific.

- a. LoradoChem will use the phrase, "For dog use only" and the phrase, "For cat use only" on the products designated for those animals.

9. **Inclusion of a website on the Labeling**

Question: EPA indicated to LoradoChem that if a website were to be noted in the labeling, EPA would need to specifically review the website content to insure compliance.

- a. LoradoChem understands the position of EPA. LoradoChem understands that website content should be in compliance with EPA standards for product promotion and advertising. If a website is included in the final labeling proposed for use with the products, LoradoChem understand the level of scrutiny that will be employed.

10. The Qualifying Verbiage for the Trademark is Wordy and Cumbersome

Question: LoradoChem found that using the active ingredient and the two active ingredients with the trademark was cumbersome and wordy as the use relates to the text on the back panel of the carton and for much of the package insert.

- a. LoradoChem proposes to keep the active ingredients descriptor at the top of the trademark on the front panel, and, of course, in the ingredient section on the front panel.
- b. LoradoChem proposes to use the active ingredients at the top of the back panel as well.
- c. For the rest of the packaging, LoradoChem plans to use the trademark followed by the phrase, "for Dogs" or "for Cats" to name the product. So the product names would be "Vetrust for Dogs," "Vetrust for Cats," "Vetrust Plus for Dogs," and "Vetrust Plus for Cats" in the text of the back panel and on the package insert as appropriate.
- d. Such economy of wording will help make the back panel more legible for the pet-owning public.

11. There is an Inconsistency with the Cat Mono Product Labeling Presentation

Question: The product for cats which has a single active ingredient of fipronil, has a slightly different graphic approach on the front panel of the pioneer product.

- a. LoradoChem proposes to change the graphic representation on the Vetrust for Cats front panel with bullet points as are the other three products. There will be no change to the wording, the points will just be represented as bullet items as on the other products.

12. There Needs to be a Suitable Qualifier for the Designation of the Distributor

Question: EPA asked for clarification on how the responsible party would be identified on the labeling.

- a. LoradoChem will hold the product licenses for the products. FidoPharm, the parent company for LoradoChem, will be the sole distributor for the products under the Vetrust trademark.
- b. The qualifying statement will read, "Available Exclusively from FidoPharm, Inc." and show the FidoPharm address.
- c. The EPA establishment Number included will be that for the production facility at Cipla in India, and is 87688-IND-01 which is the Cipla company number, followed by the country code for India, IND, followed by the facility number.
- d. The EPA registration number will be shown as 86230-1-85495, which will be the LoradoChem company number, followed by the appropriate product number, then followed by the FidoPharm company number, indicating they are a distributor for LoradoChem.

Addition of the Mosquito Claim on Product Labeling

While not discussed during the meeting, LoradoChem would like to add the mosquito claim of the pioneer to final product labeling. LoradoChem has reviewed the labeling recently approved by EPA in March, 2010 for the Frontline and Frontline Plus products. We note that a claim is present that states, "Kills mosquitoes." Since this claim was approved by EPA, regardless of its use by the pioneer, LoradoChem proposes to add this claim on our product labeling. Wording would be similar if not identical to the pioneer in their carton and package insert.

LoradoChem greatly appreciates the opportunity afforded us at the meeting with EPA on September 23, 2010, and the opportunity to get clarity on the above points prior to the final labeling review at EPA prior to product approval. As the questions are sorted, LoradoChem is happy to submit revised label texts and to supply more final printed labeling mock ups if that would assist in the review so that we can have completed labels at the time of approval. As explained in the meeting, any advance information we can receive so that final printed labels can be made more quickly will mean a great deal to LoradoChem in getting to the marketplace, commercializing these products, and to provide new, more affordable choices to the pet-owning public .

Thank you again for the opportunity to discuss these labeling issues at this stage of the product reviews. We look forward to your comments and input.

Best Regards,

Dave

Attachment I

#1 VETERINARIAN RECOMMENDED ACTIVE INGREDIENTS

FIPRONIL & S-METHOPRENE FOR DOGS

3  APPLICATOR

VE[&]RUSTTM Plus

KILLS FLEAS, FLEA EGGS, TICKS
& CHEWING LICE

- Fast action • Kills ticks, including potential Lyme disease-carrying ticks • Waterproof
- Lasting control

used on Dogs
89-132 lbs.

ACTIVE INGREDIENTS

Fipronil	9.6%
(S)-methoprene	8.6%
INERT INGREDIENTS	81.4%
TOTAL	100.0%

KEEP OUT OF REACH
OF CHILDREN
CAUTION

Contains 3-0.136 fl. oz.
(4.02 mL) applicator pipettes

This product is
not manufactured
or distributed
by Merck.
The makers of
Frontline® Plus

COMPARE TO
FRONTLINE®
PLUS
same active
ingredients*

equate[®]

Maximum Strength

Acid Reducer

Ranitidine Tablets USP, 150 mg

Prevents and Relieves

- Heartburn associated with acid and indigestion and sour stomach

150
mg

24
TABLETS

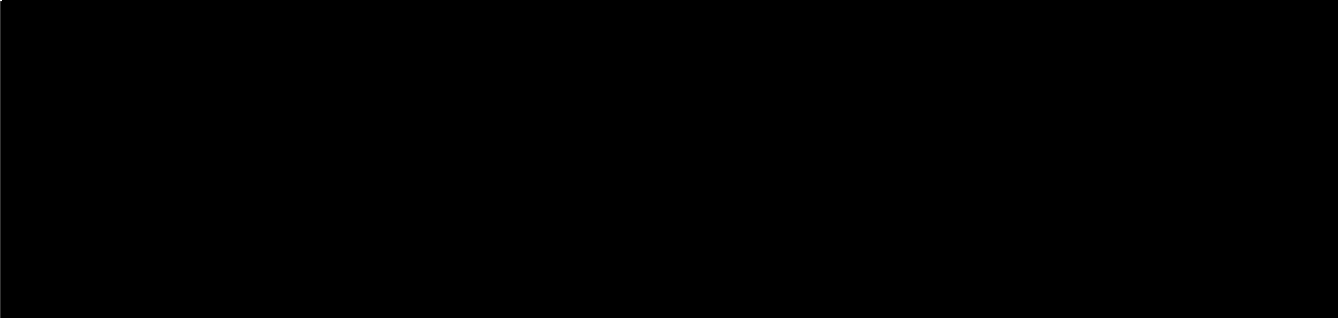
Compare
to Maximum
Strength
Zantac 150
Active
Ingredients

Attachment II

Attachment II

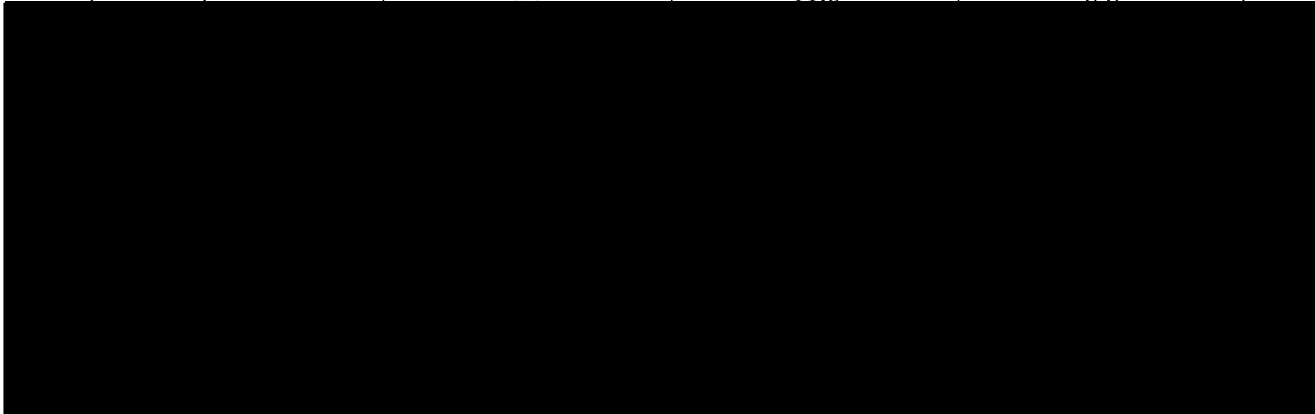
Pioneer Formulations

Components	Mono Product (% w/w)	Combo Cat (% w/w)	Combo Dog (% w/w)
<i>Fipronil</i>	9.7	9.8	9.8
<i>S-Methoprene</i>	0.0	11.8	8.8



LoradoChem Formulations

Components	Mono Product (% w/w)	Combo Cat (% w/w)	Combo Dog (% w/w)
<i>Fipronil</i>	9.7	9.8	9.8
<i>S-Methoprene</i>	0.0	11.8	8.8



Inert ingredient information may be entitled to confidential treatment

Attachment III

14, $0.9 < 1.6$ and $3.4 < 5$ at day 28, and $0.9 < 0.9$ and $2.5 < 4.8$ at day 56 in groups 1 and 2 respectively. The lesions scores were significantly lower in the fipronil group at day 28 and day 56 (Mann-Whitney test, used due to non-homogeneous variance between the groups at these two dates).

Conclusions

This controlled field trial demonstrated the effect of monthly antiparasitic treatment of all animals in the household on the control of FAD in the dog. Compared to the reference product, the 0.25% fipronil spray solution gave significantly better control of the flea burden. Reduction in pruritus and dermatological lesions was also significantly better and showed less variations within the group than observed within the reference product.

9.55

Cutaneous distribution of ^{14}C -fipronil in the dog and in the cat following a spot-on administration

P. Birckel,^a P. Cochet,^b P. Bérard^c and A. Weil^a

^aRhône Mèrieux, 4, Chemin du Calquet, 31057 Toulouse, France

^bBiotec, Orléans, France

^cÉcole Nationale Vétérinaire, Toulouse, France

Introduction

Fipronil is a new ectoparasiticide applied topically as a spray or a spot-on formulation to control fleas and ticks on dogs and cats. To investigate the localization of fipronil in the skin, ^{14}C -fipronil was topically applied as a spot-on to the dog and the cat. By means of autohistoradiography, the radioactivity was qualitatively detected in the different structures of the skin at intervals after application.

Materials and methods

The study was conducted on a Beagle dog and a European cat. The drug treatment consisted of a spot-on application of ^{14}C -fipronil to the skin at the base of the neck without shaving the area before dosing. The administered radioactivity was 500 μCi to 1 mCi per animal. Skin biopsies (5mm^2) were removed at intervals (between day 0 and day 56) from the application site and from a peripheral site far from the application site (lumbar region). Biopsies were immediately frozen and histological slices ($4-8\text{ }\mu\text{m}$ thick) were obtained from each sample. After dipping the slices in a nuclear emulsion, the distribution of the radioactivity within the skin was determined by autohistoradiography. The exposure time varied from 1.5 to 3 months, depending on the skin sampling day.

Results

Independently of the sampling time and the sampling area, the distribution of the radioactive compound was almost identical for both species. The radioactivity was widely distributed in the stratum corneum, the viable epidermis and in the pilosebaceous units. In the latter, ^{14}C -fipronil was preferentially localized in the sebaceous glands and in the epithelial layers surrounding the hairs. Radioactivity was also detected along the exposed part of the hair shaft up to 2 months after treatment, in both the area of application and the lumbar region. Radioactivity was not recorded in the dermis or in the adipose tissues (hypodermis).

Conclusions

This study demonstrated that after a spot-on application of ^{14}C -fipronil to the dog and the cat, radioactivity was particularly present in the superficial skin layers, in the pilosebaceous units and along the hairs. The significant amount of ^{14}C -fipronil recovered 2 months post-treatment in the upper cutaneous structures and along the hairs could be explained by the accumulation of radioactive material within the sebaceous glands and by the slow release of the test compound via follicular ducts. Radioactivity recovered at the lumbar zone obviously demonstrated the mechanical translocation of the radiolabelled compound from the treated area. This phenomenon may be due to the migration of fipronil by passive diffusion in the sebum covering hairs and skin. In addition, no significant radioactivity was observed in the whole dermis, pointing out the role of diffusion barrier played by the basal cells of the epidermis. The long persistence of radioactivity within the cutaneous structures and on hairs was in good accordance with the duration of activity of fipronil after a topical application in the dog and in the cat.

9.56

Therapy and prevention of flea allergy dermatitis with a permethrin spot-on formulation in 24 dogs

D.N. Carlotti,^a E. Gangutse,^b E. Bensignor,^c S.Terrier^a and D. Legend^c

^aDermatology Referral Practice, Sainte Eulalie, France

^bClinique Vétérinaire Saint Bernard, Lomme, France

^cMallinckrodt Veterinary, Meaux, France

Introduction

It has been shown that the regular use of permethrin alone with residual properties appears effective in specific therapy of flea allergy dermatitis (FAD) in dogs (Carlotti *et al.*, 1994). The aim of the study was to assess the efficacy of a spot-on permethrin formulation (Pulvex[®] Spot) in dogs with FAD.

Attachment IV

VETRUSTTM Plus

IPROXIL & S-METHOPRENE
FOR DOGS

VETRUSTTM Plus For Dogs acts fast and is an effective, lasting, waterproof, and easy-to-use treatment for control of fleas, ticks, and chewing lice on dogs and puppies weighing 89-132 lbs.

Directions For Use

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply this product. READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical use application only. Apply VETRUSTTM Plus For Dogs to dogs and puppies aged 8 weeks or older, including on breeding, pregnant, and lactating bitches, as indicated below for control of fleas, ticks (including all stages of American Dog ticks, Brown Dog ticks, Deer ticks and Lone Star ticks), and chewing lice.

How to Apply



1. Use scissors to cut along dotted line as shown. Peel back foil and remove applicator.
2. Snap the tip of the applicator away from you as shown.
3. Part the dog's hair and place the tip of the applicator to the skin level behind the neck and between the shoulders. Ensure that the entire application of VETRUSTTM Plus is contained in a single spot on the dog's skin. Be sure to squeeze the applicator thoroughly so that the entire contents are applied.

Try to keep the product from being applied superficially to the dog's hair. Use only one applicator per bottle during each treatment.

Do not touch the area where the application was made until it is dry.

VETRUSTTM Plus For Dogs may also assist in controlling sarcoptic mange infestations through multiple applications each month.

Frequency of Application

Fleas: According to research studies, adult fleas, flea eggs and flea larvae are killed up to three months following an application of Ipraxil & S-methoprene II, however, your dog or puppy is susceptible to flea infestations, so if you believe there is a risk of reinfestation, it is recommended to reapply every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply VETRUSTTM Plus For Dogs for thirty (30) days.

Same active ingredients as Frontline [®] Plus		
Ingredient	VETRUST TM Plus	Frontline [®] Plus
Ipraxil	9.8%	9.8%
S-Methoprene	9.8%	9.8%
Inert Ingredients	81.4%	81.4%
TOTAL	100%	100%

Apply to the skin behind the neck and between the shoulders. Do not apply to the face or ears.

©2010 Fort Dodge Animal Health, Inc. All rights reserved.

US Pat. 8,148,960; 8,148,961; 8,148,962; 8,148,963; 8,148,964; 8,148,965; 8,148,966; 8,148,967; 8,148,968; 8,148,969; 8,148,970; 8,148,971; 8,148,972; 8,148,973; 8,148,974; 8,148,975; 8,148,976; 8,148,977; 8,148,978; 8,148,979; 8,148,980; 8,148,981; 8,148,982; 8,148,983; 8,148,984; 8,148,985; 8,148,986; 8,148,987; 8,148,988; 8,148,989; 8,148,990; 8,148,991; 8,148,992; 8,148,993; 8,148,994; 8,148,995; 8,148,996; 8,148,997; 8,148,998; 8,148,999; 8,149,000; 8,149,001; 8,149,002; 8,149,003; 8,149,004; 8,149,005; 8,149,006; 8,149,007; 8,149,008; 8,149,009; 8,149,010; 8,149,011; 8,149,012; 8,149,013; 8,149,014; 8,149,015; 8,149,016; 8,149,017; 8,149,018; 8,149,019; 8,149,020; 8,149,021; 8,149,022; 8,149,023; 8,149,024; 8,149,025; 8,149,026; 8,149,027; 8,149,028; 8,149,029; 8,149,030; 8,149,031; 8,149,032; 8,149,033; 8,149,034; 8,149,035; 8,149,036; 8,149,037; 8,149,038; 8,149,039; 8,149,040; 8,149,041; 8,149,042; 8,149,043; 8,149,044; 8,149,045; 8,149,046; 8,149,047; 8,149,048; 8,149,049; 8,149,050; 8,149,051; 8,149,052; 8,149,053; 8,149,054; 8,149,055; 8,149,056; 8,149,057; 8,149,058; 8,149,059; 8,149,060; 8,149,061; 8,149,062; 8,149,063; 8,149,064; 8,149,065; 8,149,066; 8,149,067; 8,149,068; 8,149,069; 8,149,070; 8,149,071; 8,149,072; 8,149,073; 8,149,074; 8,149,075; 8,149,076; 8,149,077; 8,149,078; 8,149,079; 8,149,080; 8,149,081; 8,149,082; 8,149,083; 8,149,084; 8,149,085; 8,149,086; 8,149,087; 8,149,088; 8,149,089; 8,149,090; 8,149,091; 8,149,092; 8,149,093; 8,149,094; 8,149,095; 8,149,096; 8,149,097; 8,149,098; 8,149,099; 8,149,100; 8,149,101; 8,149,102; 8,149,103; 8,149,104; 8,149,105; 8,149,106; 8,149,107; 8,149,108; 8,149,109; 8,149,110; 8,149,111; 8,149,112; 8,149,113; 8,149,114; 8,149,115; 8,149,116; 8,149,117; 8,149,118; 8,149,119; 8,149,120; 8,149,121; 8,149,122; 8,149,123; 8,149,124; 8,149,125; 8,149,126; 8,149,127; 8,149,128; 8,149,129; 8,149,130; 8,149,131; 8,149,132; 8,149,133; 8,149,134; 8,149,135; 8,149,136; 8,149,137; 8,149,138; 8,149,139; 8,149,140; 8,149,141; 8,149,142; 8,149,143; 8,149,144; 8,149,145; 8,149,146; 8,149,147; 8,149,148; 8,149,149; 8,149,150; 8,149,151; 8,149,152; 8,149,153; 8,149,154; 8,149,155; 8,149,156; 8,149,157; 8,149,158; 8,149,159; 8,149,160; 8,149,161; 8,149,162; 8,149,163; 8,149,164; 8,149,165; 8,149,166; 8,149,167; 8,149,168; 8,149,169; 8,149,170; 8,149,171; 8,149,172; 8,149,173; 8,149,174; 8,149,175; 8,149,176; 8,149,177; 8,149,178; 8,149,179; 8,149,180; 8,149,181; 8,149,182; 8,149,183; 8,149,184; 8,149,185; 8,149,186; 8,149,187; 8,149,188; 8,149,189; 8,149,190; 8,149,191; 8,149,192; 8,149,193; 8,149,194; 8,149,195; 8,149,196; 8,149,197; 8,149,198; 8,149,199; 8,149,200; 8,149,201; 8,149,202; 8,149,203; 8,149,204; 8,149,205; 8,149,206; 8,149,207; 8,149,208; 8,149,209; 8,149,210; 8,149,211; 8,149,212; 8,149,213; 8,149,214; 8,149,215; 8,149,216; 8,149,217; 8,149,218; 8,149,219; 8,149,220; 8,149,221; 8,149,222; 8,149,223; 8,149,224; 8,149,225; 8,149,226; 8,149,227; 8,149,228; 8,149,229; 8,149,230; 8,149,231; 8,149,232; 8,149,233; 8,149,234; 8,149,235; 8,149,236; 8,149,237; 8,149,238; 8,149,239; 8,149,240; 8,149,241; 8,149,242; 8,149,243; 8,149,244; 8,149,245; 8,149,246; 8,149,247; 8,149,248; 8,149,249; 8,149,250; 8,149,251; 8,149,252; 8,149,253; 8,149,254; 8,149,255; 8,149,256; 8,149,257; 8,149,258; 8,149,259; 8,149,260; 8,149,261; 8,149,262; 8,149,263; 8,149,264; 8,149,265; 8,149,266; 8,149,267; 8,149,268; 8,149,269; 8,149,270; 8,149,271; 8,149,272; 8,149,273; 8,149,274; 8,149,275; 8,149,276; 8,149,277; 8,149,278; 8,149,279; 8,149,280; 8,149,281; 8,149,282; 8,149,283; 8,149,284; 8,149,285; 8,149,286; 8,149,287; 8,149,288; 8,149,289; 8,149,290; 8,149,291; 8,149,292; 8,149,293; 8,149,294; 8,149,295; 8,149,296; 8,149,297; 8,149,298; 8,149,299; 8,149,300; 8,149,301; 8,149,302; 8,149,303; 8,149,304; 8,149,305; 8,149,306; 8,149,307; 8,149,308; 8,149,309; 8,149,310; 8,149,311; 8,149,312; 8,149,313; 8,149,314; 8,149,315; 8,149,316; 8,149,317; 8,149,318; 8,149,319; 8,149,320; 8,149,321; 8,149,322; 8,149,323; 8,149,324; 8,149,325; 8,149,326; 8,149,327; 8,149,328; 8,149,329; 8,149,330; 8,149,331; 8,149,332; 8,149,333; 8,149,334; 8,149,335; 8,149,336; 8,149,337; 8,149,338; 8,149,339; 8,149,340; 8,149,341; 8,149,342; 8,149,343; 8,149,344; 8,149,345; 8,149,346; 8,149,347; 8,149,348; 8,149,349; 8,149,350; 8,149,351; 8,149,352; 8,149,353; 8,149,354; 8,149,355; 8,149,356; 8,149,357; 8,149,358; 8,149,359; 8,149,360; 8,149,361; 8,149,362; 8,149,363; 8,149,364; 8,149,365; 8,149,366; 8,149,367; 8,149,368; 8,149,369; 8,149,370; 8,149,371; 8,149,372; 8,149,373; 8,149,374; 8,149,375; 8,149,376; 8,149,377; 8,149,378; 8,149,379; 8,149,380; 8,149,381; 8,149,382; 8,149,383; 8,149,384; 8,149,385; 8,149,386; 8,149,387; 8,149,388; 8,149,389; 8,149,390; 8,149,391; 8,149,392; 8,149,393; 8,149,394; 8,149,395; 8,149,396; 8,149,397; 8,149,398; 8,149,399; 8,149,400; 8,149,401; 8,149,402; 8,149,403; 8,149,404; 8,149,405; 8,149,406; 8,149,407; 8,149,408; 8,149,409; 8,149,410; 8,149,411; 8,149,412; 8,149,413; 8,149,414; 8,149,415; 8,149,416; 8,149,417; 8,149,418; 8,149,419; 8,149,420; 8,149,421; 8,149,422; 8,149,423; 8,149,424; 8,149,425; 8,149,426; 8,149,427; 8,149,428; 8,149,429; 8,149,430; 8,149,431; 8,149,432; 8,149,433; 8,149,434; 8,149,435; 8,149,436; 8,149,437; 8,149,438; 8,149,439; 8,149,440; 8,149,441; 8,149,442; 8,149,443; 8,149,444; 8,149,445; 8,149,446; 8,149,447; 8,149,448; 8,149,449; 8,149,450; 8,149,451; 8,149,452; 8,149,453; 8,149,454; 8,149,455; 8,149,456; 8,149,457; 8,149,458; 8,149,459; 8,149,460; 8,149,461; 8,149,462; 8,149,463; 8,149,464; 8,149,465; 8,149,466; 8,149,467; 8,149,468; 8,149,469; 8,149,470; 8,149,471; 8,149,472; 8,149,473; 8,149,474; 8,149,475; 8,149,476; 8,149,477; 8,149,478; 8,149,479; 8,149,480; 8,149,481; 8,149,482; 8,149,483; 8,149,484; 8,149,485; 8,149,486; 8,149,487; 8,149,488; 8,149,489; 8,149,490; 8,149,491; 8,149,492; 8,149,493; 8,149,494; 8,149,495; 8,149,496; 8,149,497; 8,149,498; 8,149,499; 8,149,500; 8,149,501; 8,149,502; 8,149,503; 8,149,504; 8,149,505; 8,149,506; 8,149,507; 8,149,508; 8,149,509; 8,149,510; 8,149,511; 8,149,512; 8,149,513; 8,149,514; 8,149,515; 8,149,516; 8,149,517; 8,149,518; 8,149,519; 8,149,520; 8,149,521; 8,149,522; 8,149,523; 8,149,524; 8,149,525; 8,149,526; 8,149,527; 8,149,528; 8,149,529; 8,149,530; 8,149,531; 8,149,532; 8,149,533; 8,149,534; 8,149,535; 8,149,536; 8,149,537; 8,149,538; 8,149,539; 8,149,540; 8,149,541; 8,149,542; 8,149,543; 8,149,544; 8,149,545; 8,149,546; 8,149,547; 8,149,548; 8,149,549; 8,149,550; 8,149,551; 8,149,552; 8,149,553; 8,149,554; 8,149,555; 8,149,556; 8,149,557; 8,149,558; 8,149,559; 8,149,560; 8,149,561; 8,149,562; 8,149,563; 8,149,564; 8,149,565; 8,149,566; 8,149,567; 8,149,568; 8,149,569; 8,149,570; 8,149,571; 8,149,572; 8,149,573; 8,149,574; 8,149,575; 8,149,576; 8,149,577; 8,149,578; 8,149,579; 8,149,580; 8,149,581; 8,149,582; 8,149,583; 8,149,584; 8,149,585; 8,149,586; 8,149,587; 8,149,588; 8,149,589; 8,149,590; 8,149,591; 8,149,592; 8,149,593; 8,149,594; 8,149,595; 8,149,596; 8,149,597; 8,149,598; 8,149,599; 8,149,600; 8,149,601; 8,149,602; 8,149,603; 8,149,604; 8,149,605; 8,149,606; 8,149,607; 8,149,608; 8,149,609; 8,149,610; 8,149,611; 8,149,612; 8,149,613; 8,149,614; 8,149,615; 8,149,616; 8,149,617; 8,149,618; 8,149,619; 8,149,620; 8,149,621; 8,149,622; 8,149,623; 8,149,624; 8,149,625; 8,149,626; 8,149,627; 8,149,628; 8,149,629; 8,149,630; 8,149,631; 8,149,632; 8,149,633; 8,149,634; 8,149,635; 8,149,636; 8,149,637; 8,149,638; 8,149,639; 8,149,640; 8,149,641; 8,149,642; 8,149,643; 8,149,644; 8,149,645; 8,149,646; 8,149,647; 8,149,648; 8,149,649; 8,149,650; 8,149,651; 8,149,652; 8,149,653; 8,149,654; 8,149,655; 8,149,656; 8,149,657; 8,149,658; 8,149,659; 8,149,660; 8,149,661; 8,149,662; 8,149,663; 8,149,664; 8,149,665; 8,149,666; 8,149,667; 8,149,668; 8,149,669; 8,149,670; 8,149,671; 8,149,672; 8,149,673; 8,149,674; 8,149,675; 8,149,676; 8,149,677; 8,149,678; 8,149,679; 8,149,680; 8,149,681; 8,149,682; 8,149,683; 8,149,684; 8,149,685; 8,149,686; 8,149,687; 8,149,688; 8,149,689; 8,149,690; 8,149,691; 8,149,692; 8,149,693; 8,149,694; 8,149,695; 8,149,696; 8,149,697; 8,149,698; 8,149,699; 8,149,700; 8,149,701; 8,149,702; 8,149,703; 8,149,704; 8,149,705; 8,149,706; 8,149,707; 8,149,708; 8,149,709; 8,149,710; 8,149,711; 8,149,712; 8,149,713; 8,149,714; 8,149,715; 8,149,716; 8,149,717; 8,149,718; 8,149,719; 8,149,720; 8,149,721; 8,149,722; 8,149,723; 8,149,724; 8,149,725; 8,149,726; 8,149,727; 8,149,728; 8,149,729; 8,149,730; 8,149,731; 8,149,732; 8,149,733; 8,149,734; 8,149,735; 8,149,736; 8,149,737; 8,149,738; 8,149,739; 8,149,740; 8,149,741; 8,149,742; 8,149,743; 8,149,744; 8,149,745; 8,149,746; 8,149,747; 8,149,748; 8,149,749; 8,149,750; 8,149,751; 8,149,752; 8,149,753; 8,149,754; 8,149,755; 8,149,756; 8,149,757; 8,149,758; 8,149,759; 8,149,760; 8,149,761; 8,149,762; 8,149,763; 8,149,764; 8,149,765; 8,149,766; 8,149,767; 8,149,768; 8,149,769; 8,149,770; 8,149,771; 8,149,772; 8,149,773; 8,149,774; 8,149,775; 8,149,776; 8,149,777; 8,149,778; 8,149,779; 8,149,780; 8,149,781; 8,149,782; 8,149,783; 8,149,784; 8,149,785; 8,149,786; 8,149,787; 8,149,788; 8,149,789; 8,149,790; 8,149,791; 8,149,792; 8,149,793; 8,149,794; 8,149,795; 8,149,796; 8,149,797; 8,149,798; 8,149,799; 8,149,800; 8,149,801; 8,149,802; 8,149,803; 8,149,804; 8,149,805; 8,149,806; 8,149,807; 8,149,808; 8,149,809; 8,149,810; 8,149,811; 8,149,812; 8,149,813; 8,149,814; 8,149,815; 8,149,816; 8,149,817; 8,149,818; 8,149,819; 8,149,820; 8,149,821; 8,149,822; 8,149,823; 8,149,824; 8,149,825; 8,149,826; 8,149,827; 8,149,828; 8,149,829; 8,149,830; 8,149,831; 8,149,832; 8,149,833; 8,149,834; 8,149,835; 8,149,836; 8,149,837; 8,149,838; 8,149,839; 8,149,840; 8,149,841; 8,149,842; 8,149,843; 8,149,844; 8,149,845; 8,149,846; 8,149,847; 8,149,848; 8,149,849; 8,149,850; 8,149,851; 8,149,852; 8,149,853; 8,149,854; 8,149,855; 8,149,856; 8,149,857; 8,149,858; 8,149,859; 8,149,860; 8,149,861; 8,149,862; 8,149,863; 8,149,864; 8,149,865; 8,149,866; 8,149,867; 8,149,868; 8,149,869; 8,149,870; 8,149,871; 8,149,872; 8,149,873; 8,149,874; 8,149,875; 8,149,876; 8,149,877; 8,149,878; 8,149,879; 8,149,880; 8,149,881; 8,149,882; 8,149,883; 8,149,884; 8,149,885; 8,149,886; 8,149,887; 8,149,888; 8,149,889; 8,149,890; 8,149,891; 8,149,892; 8,149,893; 8,149,894; 8,149,895; 8,149,896; 8,149,897; 8,149,898; 8,149,899; 8,149,900; 8,149,901; 8,149,902; 8,149,903; 8,149,904; 8,149,905; 8,149,906; 8,149,907; 8,149,908; 8,149,909; 8,149,910; 8,149,911; 8,149,912; 8,149,913; 8,149,914; 8,149,915; 8,149,916; 8,149,917; 8,149,918; 8,149,919; 8,149,920; 8,149,921; 8,149,922; 8,149,923; 8,149,924; 8,149,925; 8,149,926; 8,149,927; 8,149,928; 8,149,929; 8,149,930;



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 13, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

IAIN WEATHERSTON
TECHNOLOGY SCIENCES GROUP, INC.
LORADOCHEM, INC.
CIRCA CENTRE, 12TH FLOOR
4061 NORTH 156TH DRIVE
GOODYEAR, AZ 85338-

PRODUCT NAME: LC-2010-2 FIPRONIL FOR DOGS
COMPANY NAME: LORADOCHEM, INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 86230-E
EPA RECEIPT DATE: 12/08/10

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 10, at (703) 305-6701.

Sincerely,

A handwritten signature in cursive script, appearing to read "P. L. Hovacek", is positioned above the typed name.

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of Chemical Safety and
Pollution Prevention

CHILD RESISTANT PACKAGING REVIEW

January 4, 2011

MEMORANDUM

Subject: Name of Pesticide Product: LC-2010-2 Fipronil for Dogs
Product Type: Insecticide (flea product)
EPA File Symbol: 86230-E
DP Barcode: D383925
Decision No.: 429489
MRIDs: 482789-01 to 05
Action Code: R310
PC Code: 129121 Fipronil

From: Breann Hanson, Biologist *B. Hanson*
Technical Review Branch (TRB)
Registration Division (RD; 7505P)

Through: Rosalind Gross, Ph.D. *Rosalind L. Gross*
TRB
RD; 7505P

To: Bonaventure Akinlosotu, RM Team 10
Insecticide Branch
Registration Division (7505P)

Applicant: LoradoChem Inc.

FORMULATION FROM LABEL:

<u>Active Ingredient:</u>	<u>% by wt</u>
129121 Fipronil	9.7

SUMMARY:

All child and senior CRP data requirements have been fulfilled for all four proposed pipette sizes for EPA Reg. No. 86230-E.

Additionally, the following recommendations were suggested in the previous TRB review: a) the label (submitted 4/21/2010) for EPA Reg. No. 86230-E needs to be corrected in the storage section of the label statement to read "Store unused application pipettes in the original **unopened** child-resistant container and....", b) the final label must show pipette sizes labeled in fl. oz., and c) the number of ml on the label should be based on [29.6ml per fl. oz. x number of fl. oz. on the pipettes].

ACTION REQUESTED:

The Risk Manager requests: "For your review: Resubmitted CRP data, MRID #s 482789-01 to 05."

BACKGROUND:

LoradoChem Inc. (herein the "registrant") has applied for registration of LC-2010-2 Fipronil for Dogs, EPA File Symbol: 86230-E. The proposed product is for control of fleas, ticks and chewing lice on dogs only. The package consists of a purple pipette and comes in 4 sizes containing either 0.023 fl. oz (0.68 mL), 0.045 fl. oz. (1.33 mL), 0.091 fl. oz. (2.69 mL) or 0.136 fl. oz. (4.03 mL) of the product inside a blister.

In the previous TRB memorandum for EPA Reg. No. 86230-E (R. Gross, DP Barcodes: 376304, 376314, 8/26/2010), the EPA reviewer determined that all submitted Senior Adult Use Effectiveness (SUAЕ) studies were inconclusive as submitted. In response, the registrant has resubmitted SUAЕ data for the three previously reviewed pipette sizes (0.045 fl. oz. (1.33 mL), 0.091 fl. oz. (2.69 mL) and 0.136 fl. oz. (4.03 mL)) for 86230-E. The Child Panel CRP Studies for those three previously submitted pipette sizes were all deemed acceptable in that review. For previous study summaries, please see directly below.

In addition, the EPA reviewer noted that data was not provided on the proposed 0.023 fl. oz sized pipette (0.68 mL). As requested, the data have been submitted in a Child Study (MRID 48278905; Study No. GLM 10177C) and a SAUE study (MRID 48278904; Study No. GLM10177S) and are reviewed herein.

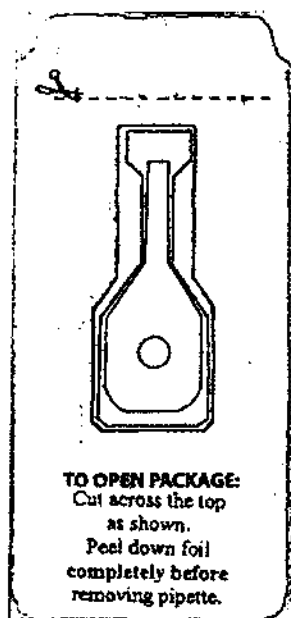
0.045 fl. oz. Pipette: In the previous TRB memorandum, the EPA reviewer could not complete their assessment of the 0.045 fl. oz sized pipette due to 75 pages of raw data sheets not being included in the original SAUE study (MRID 48013003; Study No. GLM 10053). In response, the registrant has resubmitted the SAUE CRP data (MRID 48278902; Study No. GLM 10053S) which are reviewed herein. The Child Panel CRP Study (MRID 48013005) was deemed acceptable.

0.091 fl. oz. Pipette: In the previous TRB memorandum, the EPA reviewer determined that the SUAЕ study (MRID 48013004) for the 0.091 fl. oz. sized pipette (2.69 mL) was inconclusive as submitted. In response, the registrant has resubmitted the SUAЕ CRP data (MRID 48278903; Study No. GLM 10057S) which are reviewed herein. The Child Panel CRP Study (MRID 48013006) was deemed acceptable

0.136 fl. oz. Pipette: In the previous TRB memorandum, the EPA reviewer determined that the SUAЕ study (MRID 48013002) for the 0.136 fl. oz. sized pipette (4.03 mL) was inconclusive as submitted. In response, the registrant has resubmitted the SUAЕ CRP data (MRID 48278901; Study No. GLM 10058S) which are reviewed herein. The Child Panel CRP Study (MRID 48013007) was deemed acceptable.

PACKAGING:

The package consists of a pipette containing the product inside a blister. There are 3 blisters connected to each other per card. The blister, which is the child-resistant package, is opened by the directions on the back of the blister. These directions indicate: to cut across the top of the blister along a dotted line with a scissors icon; peel down the foil on the back of the blister completely; and then remove the pipette. See diagram, below.



The pipettes are purple for the Fipronil only product, EPA Reg. No. 86230-E. The canine-product pipettes come in 4 different sizes (0.023, 0.045, 0.91, and 0.136 fl. oz.).

TOXICITY:

The toxicity of the product is based on the toxicity of Fipronil. The toxic or harmful amount of Fipronil for an 11.4 kg child is $2.5 \text{ mg/kg} \times 11.4 \text{ kg} = 28.5 \text{ mg}$. Access to a toxic or harmful amt = $28.5 \text{ mg} = 28.5 \text{ mg}$ divided by $[1028 \text{ mg/mL} \times 0.097 \text{ Fipronil}] = 0.286 \text{ mL} = \mathbf{0.29 \text{ mL}}$ for Fipronil only product, EPA Reg. No. 86230-E. Access to one pipette represents a failure for a child for all sizes greater than 0.29 mL for EPA Reg. No. 86230-E.

EPA Reg. No	Fl. Oz.	mL*	Product Density (mg/mL)	% Fipronil	mg Fipronil	# unit = tox /harmful amt
86230-E dog Fipronil	0.023	0.68	1028	9.7	67.81	1
86230-E dog Fipronil	0.045	1.33	1028	9.7	132.62	1
86230-E dog Fipronil	0.091	2.69	1028	9.7	268.24	1
86230-E dog Fipronil	0.136	4.03	1028	9.7	401.86	1

*29.6 mL = 1 fl. oz.

FAILURE:

For the purposes of CRP testing, a **child failure** is access to one blister for all sizes greater than 0.29 mL for EPA Reg. No. 86230-E.

A unit failure for the child test was defined as access to the pipette or any partial or complete access to the placebo (water) for EPA Reg. No. 86230-E.

An SAUE failure is the inability to access the pipette in the prescribed test time of 5 minutes for the first package or 1 minute for the second package, breaking or cutting the pipette that has the potential to release the contents (such as cutting into the hollow/liquid-containing part of the pipette stem) in the prescribed test time of 5 minutes for the first package or 1 minute for the second package, or accessing any amount of placebo (water) while opening the blister in the prescribed test time of 5 minutes for the first package or 1 minute for the second package.

COMMENTS and RECOMMENDATIONS:

0.023 fl. oz. Pipette

As noted in the previous TRB review, the registrant did not submit any test data for the 0.023 fl. oz canine single ai fipronil product and instead requested to bridge data from the 0.017 fl. oz. feline single ai fipronil product, EPA Reg. No. 86230-R. The TRB reviewer concluded that the data could not be bridged due to the different amounts of product contained within the packages; EPA Reg. No. 86230-R contains 0.017 fl. oz. while EPA Reg. No. 86230-E contains 0.023 fl. oz. The TRB reviewer requested that both a Child Study and SAUE study be submitted. The data were submitted in a Child Study (MRID 48278905; Study No. GLM 10177C) and a SAUE study (MRID 48278904; Study No. GLM10177S) and are reviewed below.

Child Panel CRP Study (MRID 48278905; GLM 10177C): The study involved giving each child 1 card with 3 blisters each containing a pipette with 0.023 fl. oz. of water at the start of the test.

Data Analysis: There was 1 female age calculation error. This reviewer has examined the age data provided within the report; the reported age was 42 months while the actual age is 43 months, therefore this age error does not affect the age allocations required by the regulations. The test individual is, regardless of the error, included in the required 42-44 months test group, totaling 30% of tested individuals.

Child ages, gender distributions, age allocations, as well as test site and tester requirements all adhered to the child testing regulations set forth in 16 CFR 1700.20. There was 1 child failure: a 48 month old female that exposed one pipette within the full 10 minutes of testing, after the demonstration. The study (MRID 48278905) is considered as "passing" the child test according to the sequential test chart in 16 CFR 1700.20.

SAUE Study (MRID 48278904; Study No: GLM 10177S): The study involved handing the test subjects 1 card with 3 individual blisters each containing a pipette filled with 0.023 fl. oz. of water. The test subjects were to open one blister during a 5 minute test period and another blister during a one minute test period. Scissors were made available during testing because the test directions given to the seniors called for their use.

Data Analysis: Senior ages, gender distributions, age allocations, as well as test site and tester requirements all adhered to the senior testing regulations set forth in 16 CFR 1700.20. There were 4 senior failures: a) a 57 year old male failed to properly open package "B" and snapped the neck of the pipette; b) a 69 year old male also failed to properly open package "B" and snapped the neck of the pipette; c) a 58 year old female failed to open package "B" in the required 60 seconds; and d) another 64 year old female failed to open package "B" in the required 60 seconds. This corresponds to a 96% success rate. The study (MRID 48278904) is considered as "passing" the senior test according to 16 CFR 1700.20.

Conclusion: Both child and senior SAUE CRP testing data requirements have been fulfilled for the 0.023 fl. oz. sized pipette for EPA Reg. No. 86230-E.

0.045 fl. oz. Pipette

As noted in the previous TRB review, the reviewer could not complete their assessment of the 0.045 fl. oz. canine single ai fipronil product study due to 75 pages of raw data sheets not being included in the original report (MRID 48013003; Study No. GLM 10053). The data were resubmitted in a new study (MRID 48278902; Study No. GLM 10053S) and are reviewed below. The Child Panel CRP Study (MRID 48013005) was deemed acceptable.

SAUE Study (MRID 48278902; Study No. GLM 10053S): The study involved handing the test subjects 1 card with 3 individual blisters each containing a pipette filled with 0.045 fl. oz. of water. The test subjects were to open one blister during a 5 minute test period and another blister during a one minute test period. Scissors were made available during testing because the test directions given to the seniors called for their use.

Data Analysis: There was 1 female age calculation error; a data entry error on the submitted CD. This reviewer has examined the age data provided within the report, and this test individual is properly included in the required 50-54 years of age test group, totaling 25% of tested individuals.

Senior ages, gender distributions, age allocations, as well as test site and tester requirements all adhered to the senior testing regulations set forth in 16 CFR 1700.20. There were 5 senior failures reported by the study author: a) a 53 year old female failed to properly open package "A"; b) a 52 year old female failed to properly open package "B" in the required 60 seconds; c) a 59 year old female failed to properly open package "B" in the required 60 seconds; d) a 63 year old female failed to properly open package "B" in the required 60 seconds; and e) a 62 year old male failed to properly open package "B" in the required 60 seconds. In addition, this reviewer has determined that based on additionally submitted data, package 60B, tested with a 69 year old female, should also have been reported as a failure. The pipette tested for package 60B was indented and is considered by this reviewer as damaged; the pipette should not have been used for testing. This reviewer has concluded that there were 6 total senior failures. This corresponds to a 94% success rate. The study (MRID 48278902) is considered as "passing" the senior test according to 16 CFR 1700.20.

Conclusion: Both child and senior SAUE CRP testing data requirements have been fulfilled for the 0.045 fl. oz. sized pipette for EPA Reg. No. 86230-E.

0.091 fl. oz. Pipette: As noted in the previous TRB review for the 0.091 fl. oz. canine single ai fipronil product, EPA Reg. No. 86230-E, (MRID 48013004; Study No. GLM 10057) the TRB reviewer concluded that 6 subjects exhibited "inconclusive" results. These 6 subjects were: a) a 52 year old female (package 1), b) a 54 year old female (package 15), c) a 55 year old male (package 44), d) a 56 year old male (package 48), e) a 61 year old female (package 54), and f) a 67 year old female (package 80). This reviewer has examined the additional information provided within the new study (MRID 48278903; Study No. GLM 10057S) and has concluded that the 6 packages can now be considered "successfully opened", i.e. as passing.

Conclusion: As the original data analysis concluded that there were 3 senior failures, and the additional data reviewed herein are considered as passing, this corresponds to a 97% success rate. CRP SAUE requirements have been fulfilled for the 0.091 fl. oz. sized pipette for EPA Reg. No. 86230-E.

0.136 fl. oz. Pipette: As noted in the previous TRB review for the 0.136 fl. oz. canine single ai fipronil product, EPA Reg. No. 86230-E, (MRID 48013002; Study No. GLM 10058) the TRB reviewer

concluded that 4 subjects exhibited "inconclusive" results. These 4 subjects were: a) a 61 year old female (package 57), b) a 63 year old female (package 71), c) a 60 year old male (package 86), and d) a 61 year old male (package 99). This reviewer has examined the additional information provided within the new study (MRID 48278901; Study No. GLM 10058S) and has concluded that the 4 packages can now be considered "successfully opened", i.e. as passing.

Conclusion: As the original data analysis concluded that there were 10 senior failures, and the additional data reviewed herein are considered as passing, this corresponds to a 90% success rate. CRP SAUE requirements have been fulfilled for the 0.136 fl. oz. sized pipette for EPA Reg. No. 86230-E.

CONCLUSION:

All child and senior CRP data requirements have been fulfilled for all four proposed pipette sizes for EPA Reg. No. 86230-E.

Additionally, the following recommendations were suggested in the previous TRB review: a) the label (submitted 4/21/2010) for EPA Reg. No. 86230-E needs to be corrected in the storage section of the label statement to read "Store unused application pipettes in the original **unopened** child-resistant container and....", b) the final label must show pipette sizes labeled in fl. oz., and c) the number of ml on the label should be based on [29.6ml per fl. oz. x number of fl. oz. on the pipettes].

Note to Registrant: Should any human experience/epidemiological evidence indicate a problem once the product is in the marketplace, the Agency reserves the right to reexamine this data comprehensively and to question the child resistance of the package involved.

**APPLICATION TO REGISTER LC-2010-1 FIPRONIL FOR DOGS
FOR CONTROL OF FLEAS, TICKS AND CHEWING LICE**

OPP Decision Number: D-429489

SUPPLEMENTAL SUBMISSION

ADDITION OF ALTERNATE SOURCE OF ACTIVE INGREDIENT

End-Use Product
EPA File Symbol 86230-E

VOLUME 86230-E-AS-1
ADMINISTRATIVE MATERIALS, CORRESPONDENCE, APPLICATION AND CONFIDENTIAL
STATEMENT OF FORMULA

DATA REQUIREMENTS
40 CFR 152.50

AUTHOR
Iain Weatherston, Ph.D.

DATE COMPLETED
December 7, 2010

SPONSOR
LORADOCHEM, Inc.
Cira Centre, 12th Floor
2929 Arch Street, Philadelphia, PA 16104-2891

SUBMITTED BY
Technology Sciences Group Inc.
4061 North 156th Drive Goodyear, AZ 85395

CONFIDENTIALITY CLAIMS

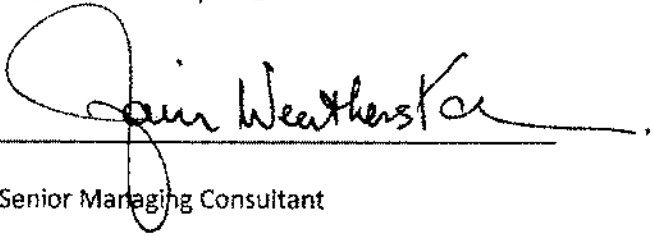
STATEMENT OF DATA CONFIDENTIALITY

Information claimed confidential on the basis of its falling within the scope of FIFRA § 10 (d)(1) [A], [B] or [C] has been removed to a confidential attachment and is cited by a cross-reference number in the body of the text.

COMPANY: LoradoChem Inc.

AGENT: Iain Weatherston, PH.D.

SIGNATURE:

A handwritten signature in black ink, appearing to read "Iain Weatherston", is written over a horizontal line. The signature is fluid and cursive.

TITLE: Senior Managing Consultant

DATE: December 7, 2010

GOOD LABORATORY PRACTICES STATEMENT

The purpose and scope of this report **DO NOT FALL UNDER** the requirements of 40 CFR 160.

CONTENTS

CONFIDENTIALITY CLAIMS	2.
GOOD LABORATORY PRACTICES STATEMENT	3.
CONTENTS	4.
LETTER OF INTRODUCTION	5.
APPLICATION FOR PESTICIDE REGISTRATION [Form 8570-1]	7.
PLACE HOLDER PAGE	8.
FORMULATOR'S EXEMPTION STATEMENT [Form 8570-27]	10.
DATA MATRIX [Form 9570-35]	11.
CONFIDENTIAL ATTACHMENT	
COVER	1.
CROSS REFERENCE PAGE	2.
CONFIDENTIAL STATEMENT OF FORMULA	3.

Richard Gebken
Product Manager, Team 10
U.S. EPA – OPP – RD – IB
One Potomac Yard
2777 South Crystal Drive
ARLINGTON, VA 22202

December 7, 2010

SUBJECT: Supplemental Submission
Addition of Alternate Source of Active Ingredient to the Registration
Package for LC-2010-2 FIPRONIL FOR DOGS

COMPANY: LoradoChem Inc., Cira Centre 12th Floor, 2929 Arch Street, Philadelphia,
PA 16104-2891.

CONTACT: Iain Weatherston, Ph.D., Technology Sciences Group Inc., 4061 North
156th Drive, Goodyear, AZ 85395. [623-535-4060]
iweatherston@tsgusa.com.

PRODUCT: LC-2010-2 FIPRONIL FOR DOGS [86230-E]

OPP DECISION NUMBER: D-429489

Dear Mr. Gebken:

As agent for, and on behalf of LoradoChem Inc., I submit for expedited review and approval, as decided at the November 22, 2010 meeting with the Registration Division Director, Associate Director, OGC attorney and the Branch Chiefs of IB and TRB, an application to add an alternate source of technical fipronil to the current pending registration for the subject product.

In addition to this letter, this Volume 86230-E-AS-1 contains:-

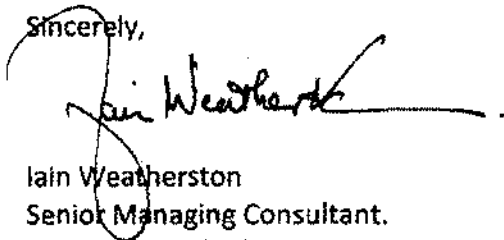
- A fully executed Application for Pesticide Registration [Form 8570-1]
- Formulators Exemption Statement [Form 8570-27]
- Data matrix [Form 8570-35]
- Confidential Statement of Formula [8570-4]

There is no label included, since the change of source of technical active ingredient does not impact the labeling.

In addition to the Administrative volume, the submission also includes an abbreviated product chemistry volume, Volume 86230-E-AS-2 as requested in a telephone call on Friday December 3, 2010 by Dan Kenny after consulting with Shyam Mathur.

Should you require any further information, or have any questions, please do not hesitate to contact me by e-mail at iweatherston@tsgusa.com or by telephone at 623-535-4060.

Sincerely,

A handwritten signature in black ink, appearing to read "Iain Weatherston", with a long horizontal stroke extending to the right.

Iain Weatherston
Senior Managing Consultant.
Agent to LoradoChem Inc.

Please read instructions on reverse before completing form.


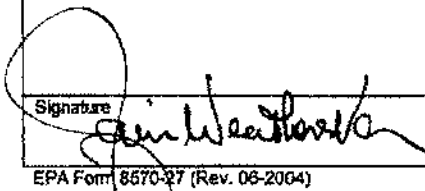
Form Approved, OMB No. 2070-0060, Approval expires 2-28-95

<div style="display: inline-block; vertical-align: middle;"> United States Environmental Protection Agency Washington, DC 20460 </div>		<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 86230-E		2. EPA Product Manager RICHARD GEBKEN	
4. Company/Product (Name) LORADO CHEM INC. / LC-2010-2 FIPRONIL FOR DOGS		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) LoradoChem Inc., Cira Centre, 12th Floor, 2929 Arch St., Philadelphia, PA 16104-2871 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
Section - II			
<input checked="" type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.	
Explanation: Use additional page(s) if necessary. (For section I and Section II.) Submission of alternate source of fipronil active ingredient to expedite the end-use product approval as agreed to at the November 22, 2010 between the applicant and Lois Rossi.			
Section - III			
1. Material This Product Will Be Packaged in:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	
5. Location of Label Directions <input type="checkbox"/> _____		6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____	
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name IAIN WEATHERSTON		Title SENIOR MANAGING CONSULTANT	
Telephone No. (Include Area Code) 623-535-4060			
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			8. Date Application Received (Stamped)
2. Signature 		3. Title SENIOR MANAGING CONSULTANT	
4. Typed Name IAIN WEATHERSTON		5. Date November 30, 2010	

PLACE HOLDER PAGE

CROSS-REFERENCE NUMBER	[1]
DELETED PAGE:	Immediately following this page
PAGE DELETED:	9
REASON FOR DELETION:	Confidential Statement of Formula
FIFRA REFERENCE:	§ 10 (d)(1) (c)

Form approved. OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.

		
<p>United States Environmental Protection Agency Washington, DC 20460 Formulator's Exemption Statement (40 CFR 152.85)</p>		
Applicant's Name and Address LoradoChem, Inc., Cira Centre 12th Floor, 2929 Arch Street, Philadelphia, PA 16104-2891.	EPA File Symbol/Registration Number 86230-E	
	Product Name LC-2010-2 Fipronil for Dogs	
	Date of Confidential Statement of Formula (EPA Form 8570-4) 11/30/2010	
<p>As an authorized representative of the applicant for registration of the product identified above, I certify that:</p> <p>(1) This product contains the following active ingredient(s): Fipronil</p> <p>(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).</p> <p>(3) Indicate by checking (A) or (B) below which paragraph applies:</p> <p><input checked="" type="checkbox"/> (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).</p> <p style="text-align: center;">OR</p> <p><input type="checkbox"/> (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.</p> <p>(4) The following active ingredients in this product qualify for the formulator's exemption.</p>		
Source		
Active Ingredient Fipronil [CAS# 120068-37-3]	Product Name Fipronil Technical	Registration Number 87650-R
Signature 	Name and Title Iain Weatherston /Sr. Manag. Cslt.	Date 11/30/2010

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
Copy 2 - Applicant copy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0080

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 11/30/2010

EPA Reg No./File Symbol 86230-E

Page 1 of 3

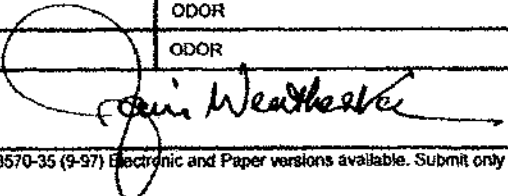
Applicant's/Registrant's Name & Address

LORADOCEM INC., CIRA CENTRE 12TH FLOOR, PHILADELPHIA, PA 16104-2891

Product

LC-2010-2 FIPRONIL FOR DOGS

Ingredient FIPRONIL

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	PRODUCT IDENTITY AND COMPOSITION		LORADOCEM INC	OWN	V86230-E-AS-2
830.1550	PRODUCT IDENTITY AND COMPOSITION	48013001	LORADOCEM INC	OWN	BRIDGE
830.1600	DESCRIPTION OF STARTING MATERIALS		LORADOCEM INC	OWN	V86230-E-AS-2
830.1600	DESCRIPTION OF STARTING MATERIALS	48013001	LORADOCEM INC	OWN	BRIDGE
830.1650	FORMULATION PROCESS		LORADOCEM INC	OWN	V86230-E-AS-2
830.1650	FORMULATION PROCESS	48013001	LORADOCEM INC	OWN	BRIDGE
830.1750	CERTIFIED LIMITS		LORADOCEM INC.	OWN	see CSF
830.1800	ENFORCEMENT ANALYTICAL METHOD		LORADOCEM INC.	OWN	V86230-E-AS-2
830.1800	ENFORCEMENT ANALYTICAL METHOD	48013001	LORADOCEM INC	OWN	BRIDGE
830.6302	COLOR		LORADOCEM INC	OWN	V86230-E-AS-2
830.6302	COLOR	48013001	LORADOCEM INC	OWN	BRIDGE
830.6303	PHYSICAL STATE		LORADOCEM INC	OWN	V86230-E-AS-2
830.6303	PHYSICAL STATE	48013001	LORADOCEM INC	OWN	BRIDGE
830.6304	ODOR		LORADOCEM INC	OWN	V86230-E-AS-2
830.6304	ODOR	48013001	LORADOCEM	OWN	BRIDGE
Signature				Name and Title	Date
				Iain Weatherston Sr. Managing Consultant	11/30/2010

Form Approved OMB No. 2070-0060



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 11/30/2010

EPA Reg No./File Symbol 86230-E

Page 2 of 3

Applicant's/Registrant's Name & Address

LORADOCHM INC., CIRA CENTRE 12TH FLOOR, PHILADELPHIA, PA 16104-2891

Product

LC-2010-2 FIPRONIL FOR DOGS

Ingredient FIPRONIL

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6313	STABILITY TO TEMP., METALS & METAL IONS				NOT REQUIRED
830.6314	OXIDATION/REDUCTION POTENTIAL		LORADOCHM INC	OWN	V86230-E-AS-2
830.6314	OXIDATION/REDUCTION POTENTIAL	48013001	LORADOCHM INC	OWN	BRIDGE
830.6315	FLAMMABILITY		LORADOCHM INC	OWN	V86230-E-AS-2
830.6315	FLAMMABILITY	48013001	LORADOCHM INC	OWN	BRIDGE
830.6316	EXPLODABILITY		LORADOCHM INC	OWN	V86230-E-AS-2
830.6316	EXPLODABILITY		LORADOCHM INC.	OWN	BRIDGE
830.6317	STORAGE STABILITY		LORADOCHM INC.	OWN	IN PROGRESS
830.6319	MISCIBILITY				NOT REQUIRED
830.6320	CORROSION CHARACTERISTICS		LORADOCHM INC	OWN	IN PROGRESS
830.6321	DIELECTRIC BREAKDOWN CONSTANT		LORADOCHM INC	OWN	V86230-R-AS-2
830.6321	DIELECTRIC BREAKDOWN CONSTANT	48013001	LORADOCHM INC	OWN	BRIDGE
830.7000	pH		LORADOCHM INC	OWN	V86230-R-AS-2
830.7000	pH	48013001	LORADOCHM INC	OWN	BRIDGE
830.7050	UV/VISIBLE ABSORPTION		LORADOCHM	OWN	NOT REQUIRED

Signature

Iain Weatherston

Name and Title

Iain Weatherston Sr. Managing Consultant

Date

11/30/2010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460						Form Approved OMB No. 2070-0060
<p>Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.</p>						
DATA MATRIX						
Date 11/30/2010				EPA Reg No./File Symbol 86230-E		Page 3 of 3
Applicant's/Registrant's Name & Address LORADO CHEM INC., CIRA CENTRE 12TH FLOOR, PHILADELPHIA, PA 19104-2891				Product LC-2010-2 FIPRONIL FOR DOGS		
Ingredient FIPRONIL						
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
830.7100	VISCOSITY		LORADO CHEM INC	OWN	V86230-E-AS-2	
830.7100	VISCOSITY	48013001	LORADO CHEM INC	OWN	BRIDGE	
830.7200	MELTING POINT/RANGE				NOT REQUIRED	
830.7220	BOILING POINT/RANGE				NOT REQUIRED	
830.7300	DENSITY/BULK DENSITY/SPECIFIC GRAVITY		LORADO CHEM INC	OWN	V86230-E-AS-2	
830.7300	DENSITY/BULK DENSITY/SPECIFIC GRAVITY	48013001	LORADO CHEM INC	OWN	BRIDGE	
830.7373	DISSOCIATION CONSTANT				NOT REQUIRED	
830.7550/60/70	PARTITION COEFFICIENT				NOT REQUIRED	
830.7840/60	WATER SOLUBILITY				NOT REQUIRED	
830.7950	VAPOR PRESSURE				NOT REQUIRED	
ALL OTHER GUIDELINE	REQUIREMENTS ARE SATISFIED BY THE CITE-ALL	METHOD OF	DATA SUPPORT AND THE LIST OF			
COMPANIES SENT OFFER-TO-PAY	LETTERS IS BRIDGED FROM THE LIST GIVEN IN THE	DOCUMENT	WITH MRID 48013000			
Signature 			Name and Title Iain Weatherston Sr. Managing Consultant		Date 11/30/2010	

APPLICATION TO REGISTER LC-2010-2 FIPRONIL FOR DOGS

FOR CONTROL OF FLEAS, TICKS AND CHEWING LICE

OPP Decision Number: D-429489

SUPPLEMENTAL SUBMISSION

ADDITION OF ALTERNATE SOURCE OF ACTIVE INGREDIENT

End-Use Product
EPA File Symbol 86230-E

VOLUME 86230-E-AS-2

SUPPLEMENTAL PRODUCT CHEMISTRY

DATA REQUIREMENTS

OPPTS 830.1550, 830.1600, 830.1650, 830.1670, 830.1750, 830.1800 AND REQUIRED RESPONSES TO
OPPTS 830.6000/7000

AUTHOR

Iain Weatherston, Ph.D.

DATE COMPLETED

December 7, 2010

LABORATORY

Cipla Ltd.
Plot No. M12, Indore Special Economic Zone, Phase II, Pithampur, District Dhar
Madhya Pradesh 454775, India

STUDY NUMBER

Cipla-2009F Supplemental

SPONSOR

LORADO CHEM, Inc.
Cira Centre, 12th Floor
2929 Arch Street, Philadelphia, PA 16104-2891

SUBMITTED BY

Technology Sciences Group Inc.
4061 North 156th Drive Goodyear, AZ 85395

CONFIDENTIALITY CLAIMS

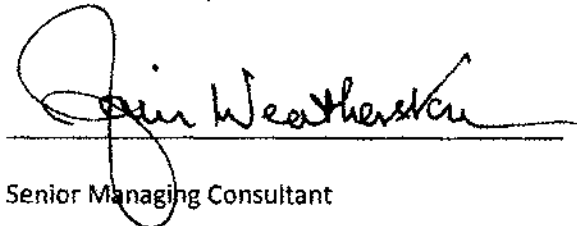
STATEMENT OF NO DATA CONFIDENTIALITY

No claim of data confidentiality is made for any information contained in this volume on the basis of its falling within the scope of FIFRA § 10 (d)(1)[A], [B] or [C]

COMPANY: LoradoChem Inc.

AGENT: Iain Weatherston, PH.D.

SIGNATURE:

A handwritten signature in black ink, appearing to read "Iain Weatherston", is written over a horizontal line.

TITLE: Senior Managing Consultant

DATE: December 7, 2010

GOOD LABORATORY PRACTICES STATEMENT

This is a supplemental report to the original report identified by MRID 48013001 and the GLP statement in the original report is also operative in this current report

CONTENTS

CONFIDENTIALITY CLAIMS	2.
GOOD LABORATORY PRACTICES STATEMENT	3.
CONTENTS	4.
INTRODUCTION	5.
RESPONSE TO PRODUCT CHEMISTRY GUIDELINES	6.

INTRODUCTION

This volume is being submitted in support of the registration of LC-2010-2 Fipronil for Dogs. The addition of an alternate Fipronil source was discussed at a meeting of the registrant with Lois Rossi, members of her office staff, an OGC attorney and the Branch Chiefs of IB and TRB, and the registrant. The format of this volume has been discussed between the Branch Chiefs of IB and TRB and the chemistry reviewers. The understanding is that the product chemistry reports from the initial application may be bridged to end-use products, using the alternate source of active ingredient (fipronil) because the two technical materials are substantially similar and all of the work (methods of formulation, analysis, formulation of impurities and physical/chemical characteristics) was carried out at the same facility and laboratory where the original data was developed.

OPPTS 830.

1550	Product identity and composition	bridged from MRID 48013001
1600	Description of starting materials	bridged from MRID 48013001
	Product Composition	
	<u>Active Ingredient</u>	Fipronil Technical
		EPARN pending as 87650-1
		Purity 98.5%
		CAS# 120068-37-3
		Supplier Fipronext Solutions Inc., Pleasanton, CA 94587
		Nominal conc. 9.70%
		UCL 10.19%
		LCL 9.22%
		MSDS attached in appendix.
	<u>Other ingredients</u>	all bridged from MRID 48013001
1650	Discussion of formulation process	bridged from MRID 48013001
1670	Discussion of impurities	bridged from MRID 48013001
1700	Preliminary analysis	not required – end-use product
1750	Certified limits	see CSF in V86230-E-AS-1
1800	Enforcement analytical method	bridged from MRID 48013001
1900	Submittal of samples	will do if requested.
6302	Color	bridged from MRID 48013001
6303	Physical state	bridged from MRID 48013001
6304	Odor	bridged from MRID 48013001
		not required see Table 2 in 830.1000.
6313	Stability to temp., metals & metal ions	bridged from MRID 48013001
		not required see Table 2 in 830.1000.
6314	Oxidation/reduction – chemical incompatibility	bridged from MRID 48013001
		not required see Table 2 in 830.1000.
6315	Flammability	bridged from MRID 48013001
		[51°C]
6316	Explosibility	bridged from MRID 48013001
		Not required – product is not potentially explosive.

6317	Storage stability	study initiated in final packaging at Cipla Ltd., Mumbai
6319	Miscibility	not required, product is not an emulsifiable liquid.
6320	Corrosion characteristics	study initiated in final packaging at Cipla Ltd., Mumbai
6321	Dielectric breakdown constant	not required – product is not labeled for use around electrical equipment.
7000	pH	not required – product is not dispersible in water
7050	UV/visible absorption	not required for end-use products
7100	Viscosity	bridged from MRID 48013001
7200	Melting point/range	8.70@ 30 rpm @ room temp.
7220	Boiling point/range	not required for end-use products
7300	Density/relative density/specific gravity	not required for end-use products
7370	Dissociation constant	bridged from MRID 48013001
7550/60/70	Partition coefficient	1.030 g/ml
7840/60	Water solubility	not required for end-use products
7950	Vapor pressure	not required for end-use products

APPENDIX

MSDS FOR FIPRONEXT SOLUTIONS LTD., TECHNICAL FIPRONIL

Fipronext Solutions Inc.

3259 Harvey Ct, Pleasanton, CA 94587 USA

MSDS OF Fipronil

1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND OF THE COMPANY / UNDERTAKING

Commercial product name: Fipronil, Phenyl Pyrazole
Supplier: Fipronext Solutions Inc.
Emergency telephone number: 1-510-579-7685

2. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical characterization: Fipronil, Phenyl Pyrazole
Synonyms:
5-Amino-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(1*R*,5)-(trifluoromethyl)sulfinyl]-1*H*-pyrazole-3-carbonitrile
Dangerous substances: None
Hazardous components: None
Empirical Formula: $C_{12}H_4Cl_2F_6N_4OS$
CAS number: 120068-37-3

3. HAZARDS IDENTIFICATION

Emergency Overview:

Warning: May be fatal if absorbed through skin.
May be fatal if inhaled.
May be fatal if swallowed.
May cause moderate but temporary irritation to the eyes.
KEEP OUT OF REACH OF CHILDREN.
KEEP OUT OF REACH OF DOMESTIC ANIMALS.

Potential Health Effects:

Primary route of exposure: eye and skin contact, ingestion and inhalation.
Acute toxicity: Moderately toxic after single ingestion or short-term skin contact. Slightly toxic after short-term inhalation.
Irritation: Slight irritation to skin, moderately irritation to the eyes.

4. FIRST-AID MEASURES

Inhalation: Remove victim to fresh air, administer oxygen as needed. If victim is not breathing, administer artificial respiration or CPR and contact a physician.
Skin contact: wash well with mild soap and water. Remove any contaminated clothing. Flush skin surface with additional water.
Eye contact: Flush eyes with plenty amounts of fresh water for at least 15 minutes.

Fipronext Solutions Inc.

3259 Harvey Ct, Pleasanton, CA 94587 USA

Ingestion: Flush mouth with plenty amounts of water and contact a physician. Do not swallow rinse water.

5. FIRE-FIGHTING MEASURES

Suitable fire extinguishing media: Use extinguishing media appropriate to surrounding fire. No special equipment or procedures are required.

Unusual hazards: Not known

Special exposure hazards: Risk of dust explosion.

Special protective equipment for firefighters: Respiratory protector with gas filter or breathing apparatus recommended.

6. ACCIDENTAL RELEASE MEASURES

Individual precautions: Wear protective cloth.

Environmental precautions: Hand over spilled material to recycling or to waste disposal.

Procedure of cleaning/take up: Take up by mechanical means. Flush remainder with water

7. HANDLING AND STORAGE

Avoid dust formation. Store in a dry and cool place in an unopened package.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Recommended personal protective equipment:

Respiratory protection: Respiratory protector approved for this type of dust

Hand protection: Impermeable gloves

Eye protection: Protective goggles.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form: powder

· Color: white or slightly light yellow

· Odor: low odor.

· Melting point/Melting range: 196-200°C

· Insoluble in DMF: not more than 0.5%

· Heavy Metals: not more than 10ppm

· Basicity: not more than 0.2%

Fipronext Solutions Inc.

3259 Harvey Ct, Pleasanton, CA 94587 USA

10. STABILITY AND REACTIVITY

Have a shelf life of approximately 2 years in an unopened container. **STABLE.**

11. TOXICOLOGICAL INFORMATION

If handling accordingly with protective measures and with personal protective equipment no hazards health. Although avoid inhalation.

12. ECOLOGICAL INFORMATION

Product should not get into water without pre-treatment in an adapted, biological sewage work.

13. DISPOSAL CONSIDERATIONS

Waste disposal must be in accordance with appropriate local regulations. Do not re-use empty containers.

14. TRANSPORT INFORMATION

UN No.	Not applicable
Sea	applicable
Road/rail	applicable
Air	Not applicable

15. REGULATORY INFORMATION

Registration status: TSCA registered.

OSHA Hazardous category: Acute target organ effects reported, Toxic-oral, Toxic-dermal, Highly Toxic-inhalation;

SARA hazard categories: acute, chronic

State Regulations:

CA Prop. 65: no listed.

Fipronext Solutions Inc.

3259 Harvey Ct, Pleasanton, CA 94587 USA

16. OTHER INFORMATION

The information contained in this Safety Data Sheet, as of the issue date, is believed to be true and correct. However, the accuracy or completeness of this information and any recommendations or suggestions are made without warranty or guarantee. Since the conditions of use are beyond the control of our company, it is the responsibility of the user to determine the conditions of safe use of this product. The information in this sheet does not represent analytical specifications, for which please refer to our technical data sheet.

APPLICATION TO REGISTER LC-2010-2 FIPRONIL FOR DOGS
FOR CONTROL OF FLEAS, TICKS AND CHEWING LICE

ADDITION OF ALTERNATE SOURCE OF ACTIVE INGREDIENT

End-Use Product
EPA File Symbol 86230-E

VOLUME 86230-E-AS-1CA

CONFIDENTIAL ATTACHMENT

DATA REQUIREMENTS
40 CFR 152.50

AUTHOR
Iain Weatherston, Ph.D.

DATE COMPLETED
November 30, 2010

SPONSOR
LORADO CHEM, Inc.
Cira Centre, 12th Floor
2929 Arch Street, Philadelphia, PA 16104-2891

SUBMITTED BY
Technology Sciences Group Inc.
4061 North 156th Drive Goodyear, AZ 85395

CROSS-REFERENCE PAGE

CROSS-REFERENCE NUMBER	[1]
DELETED PAGE:	Immediately following this page
PAGE DELETED:	9
REASON FOR DELETION:	Confidential Statement of Formula
FIFRA REFERENCE:	§ 10 (d)(1) (c)



Here
David Petrick to: Bonaventure Akinlosotu

12/09/2010 12:00 PM

Dear BA, We are in town. See you at 2 PM. Dave

Sent from my iPhone



See you shortly
David Petrick to: Bonaventure Akinlosotu
Cc: Marion Johnson

12/09/2010 01:19 PM

Dear BA,

We will see you in the lobby before the 2 PM meeting.

Thanks.

Dave

Re: Proposed Alternate Brand Names for the LoradoChem Products

Kimberly Nesci to: Bonaventure Akinlosotu

Cc: Clayton Myers, Marion Johnson, Mark Suarez, Richard Gebken

12/10/2010 03:54 PM

Hi all:

[Redacted]

Petrwick?

Bonaventure Akinlosotu

My suggestion:

[Redacted]

12/10/2010 03:49:58 PM

From: Bonaventure Akinlosotu/DC/USEPA/US
To: Marion Johnson/DC/USEPA/US@EPA, Richard Gebken/DC/USEPA/US@EPA
Cc: Kimberly Nesci/DC/USEPA/US@EPA, Clayton Myers/DC/USEPA/US@EPA, Mark Suarez/DC/USEPA/US@EPA
Date: 12/10/2010 03:49 PM
Subject: Re: Proposed Alternate Brand Names for the LoradoChem Products

My suggestion:

[Redacted]

Your thoughts?

Thx, B.A




-----David Petrick <davidpetrick@comcast.net> wrote: -----

To: Bonaventure Akinlosotu/DC/USEPA/US@EPA, Marion Johnson/DC/USEPA/US@EPA, Richard Gebken/DC/USEPA/US@EPA
From: David Petrick <davidpetrick@comcast.net>
Date: 12/10/2010 01:50PM
Cc: Alex Kaufman <akaufman@velcera.com>, Dennis Steadman <dsteadman@velcera.com>, Iain Weatherston <IWeatherston@TSGUSA.COM>
Subject: Proposed Alternate Brand Names for the LoradoChem Products

Dear Marion, Richard and Bonaventure,

Thank you very much for a productive and EXTREMELY helpful meeting yesterday. We appreciate the clarity of the comments and the assurance of the direction provided. As indicated yesterday, I will be sending along the re-typed Master Label Monday.

As a start, however, as we also discussed yesterday, here are three more trademarks we would propose to use for the products (mono and Combo)

 PetArmor	PetArmor Plus
 TrustGard	TrustGard Plus
 Velcera Fipronil	Velcera Fipronil Plus (S-Methoprene)

* Internal deliberative information *

We would appreciate feedback as soon as possible from you so that Alex can get the label "plates" made up with suitable TMs so you will have those when you need them as well.

Again, many thanks and I will be in touch Monday by sending along the new Master Labeling Text.

Best Regards,

Dave

~~DRAFT~~

Agency's response to LoradoChem's rebuttal to Agency's preliminary comments on the proposed labeling for four (4) new fipronil-containing spot-on EPs (86230 – R, E, G & U) in dogs and cats

N/B: With reference to Agency's meeting with the registrant on September 23, 2010; and Agency's Internal mtg (RD) on December 7, 2010.

1. Use of the trademark "Vetrust" for the products:

Unacceptable: The Agency believes the name "VETRUST" ("Trusted by veterinarians?"), including the caduceus conveys and/or implies false or misleading claims (e.g., heightened safety and efficacy, etc). The name implies that the product is an animal veterinary drug.

2. Claims made about the active ingredient:

Carton's Front Panel: You may retain the round, visible circle with the statement "***Compare to Frontline (or Frontline Plus) same active ingredient(s).***"

Carton's Back Panel: Based on determinations made by the label consistency workgroup, the ingredient comparison chart (that compares products' active ingredients) is unacceptable.

3. Supporting information concerning the use of "Waterproof":

Please provide efficacy data to support the "***waterproof***" claim, or cite-all?

4. Use of the phrase, "#1 Veterinarian Recommended Active Ingredient(s)":

Delete this comparative statement or provide appropriate supporting data to substantiate claim. The data cited in your rebuttal indicates sales ranking, not a ranking of veterinarian's recommendations.

5. Use of "Other" vs. "Inerts" in the Ingredient Statement

Although the Agency prefers the term "***Other***", especially for this type of products (i.e., spot-on), you may retain the term "***Inerts***" to designate the proportion of the finished products that are non-active components.

6. Directions to Instruct the Consumer for Opening the Packaging:

Deferred to the Child Resistant Packaging Team for final decisions.

7. Use of "Applicators" vs. "Applicator Pipettes" on the labeling:

Tentative Response (Deferred to the Child Resistant Packaging Team for final decisions):

Use either "***Applicator Pipette***" or "***Applicator***", and not both. Interchanging both will confuse the consumer/pet-owner. *Pipette everywhere*

8. Use of the phrase "For animal use only" on the bottom flap of the carton:

Revise the statement "***For animal use only***" to read "***For dog use only***" or "***For cat use only***", appropriately on the products designated for each species.

Pipette everywhere

9. **Inclusion of a website on the Labeling:**

OK
You may retain the website on the labeling. Thank you for your acknowledgment of the Agency's concerns, "*LoradoChem understands that website content should be in compliance with EPA standards for product promotion and advertising. If a website is included in the final labeling proposed for use with the products, LoradoChem understand the level of scrutiny that will be employed*".

10. **The Qualifying Verbiage for the Trademark is Wordy and Cumbersome**

OK
Question: LoradoChem found that using the active ingredient and the two active ingredients with the trademark was cumbersome and wordy as the use relates to the text on the back panel of the carton and for much of the package insert.

- LoradoChem proposes to keep the active ingredients descriptor at the top of the trademark on the front panel, and, of course, in the ingredient section on the front panel.
- LoradoChem proposes to use the active ingredients at the top of the back panel as well.
- For the rest of the packaging, LoradoChem plans to use the trademark followed by the phrase, "for Dogs" or "for Cats" to name the product. So the product names would be "Vetrust for Dogs," "Vetrust for Cats," "Vetrust Plus for Dogs," and "Vetrust Plus for Cats" in the text of the back panel and on the package insert as appropriate.
- Such economy of wording will help make the back panel more legible for the pet-owning public.

EPA's Response: Acceptable, as long as "Vetrust" is changed to another trade name.

(Tentative, pending discussions) Please also increase the font size of the word "dog" or "cat" to the size of the trademark, consistent with the Agency's initiatives related to pet spot-on products.

11. **There is an Inconsistency with the Cat Mono Product Labeling Presentation:**

OK
Question: The product for cats which has a single active ingredient of fipronil, has a slightly different graphic approach on the front panel of the pioneer product.

- LoradoChem proposes to change the graphic representation on the Vetrust for Cats front panel with bullet points as are the other three products. There will be no change to the wording, the points will just be represented as bullet items as on the other products.

EPA's Response: Acceptable (Tentative, pending discussions)

12. **There Needs to be a Suitable Qualifier for the Designation of the Distributor:**

Question: EPA asked for clarification on how the responsible party would be identified on the labeling.

- LoradoChem will hold the product licenses for the products. FidoPharm, the parent company for LoradoChem, will be the sole distributor for the products under the Vetrust trademark.
- The qualifying statement will read, "Available Exclusively from FidoPharm, Inc." and show the FidoPharm address.

Revisit

- 01/
- c. The EPA establishment Number included will be that for the production facility at Cipla in India, and is 87688-IND-01 which is the Cipla company number, followed by the country code for India, IND, followed by the facility number.
 - d. The EPA registration number will be shown as 86230-1-85495, which will be the LoradoChem company number, followed by the appropriate product number, then followed by the FidoPharm company number, indicating they are a distributor for LoradoChem.

EPA's Response: Acceptable ??? (Tentative, pending discussions)

01/ **Addition of the Mosquito Claim on Product Labeling:**

The mosquito claim is acceptable, provided relevant efficacy data are cited to support this claim. (or cite-all)?

Other Labeling Comments:

A. Cat Products:

- 1. To address dosing concerns:
 - a. Provide additional directions for use on the largest product size on what to do for very large animals to prevent consumers from over-dosing or double-dosing very large cats.
 - b. Consider adding a lower weight limit to the small cat product label. *Suggested*
- 2. To address **concerns about cat exposure to dog products:**
 - a. Brand names: Increase the size of the word "cat" to the same size as the Brand Name
- 3. To address **concerns about labeling clarity:**
 - a. Use the word "ONLY" when referring to cat size and age. In addition, this must appear on the front panel. *Suggested*
Examples:
 - "For use ONLY on cats 9 lbs and over"
 - "For use ONLY on cats 8 weeks and older"
 - b. Weight/Age Restrictions:
Ranges must appear on product vials.

01/11
Make Age
B. Dog Products:

- 1. To address dosing concerns:
 - a. Consider adding a lower weight limit to the small dog product label.
- 2. To address **concerns about cat exposure to dog products:**
 - a. Brand names: Increase the size of the word "dog" to the same size as the Brand Name

3. To address **concerns about labeling clarity**:

- a. Use the word "ONLY" when referring to dog size and age. In addition, this must appear on the front panel.

Examples:

- "For use ONLY on dogs larger than 16 lbs"
- "For use ONLY on dogs 8 weeks and older"

- b. Weight/Age Restrictions:

Ranges must appear on product vials.

B. Miscellaneous Labeling Comments:

1. In "DFU", item #3 under "How to apply": Revise the statement "Try to keep the product from being applied superficially on the dog's /cat's hair" to read "Do not apply the product superficially to the dog's /cat's hair".
2. Remove statement about surface distribution or provide appropriate supporting data/information to substantiate claim. *Code back to*
3. Delete marketing claims that implies the product retains efficacy by accumulating in the hair follicles.
4. Change all application instructions that state "Administration" to "Apply". *in accordance with DFU*
5. Delete "exposure to sunlight" from the statement "Please note that there is no need to reapply . . . in those conditions – Ambiguous."
6. Delete sarcoptic mange statement (including the multiple applications) or provide appropriate supporting data/information to substantiate claim. *Prior product.*
7. Include weight and age limits on "Care Card" ~~front, back panels.~~ *panel.*
8. Include lower age limits on all dog products, except 40 lb +. Some very large breeds can have puppies that approach a 30 lb weight at 8 weeks old. (Check with Kit)

will put in weight range

9082513432

to:

Bonaventure Akinlosotu

12/09/2010 09:42 AM

Show Details

Dear BA, I'm not sure my first message got through. We will be there. Attending will be Dennis Steadman, Alex Kaufman and me. See you just before 2 PM. If you need to reach me, call 908.251.3432. Dave



9082513432 t
o Bonaventure Akinlosotu
:

12/09/2010 09:37 AM

Dear Bonaventure , Sorry I misunderstood about today. On the train now. Who will attend from EPA? Please send response to davidpetrick@comcast.net

9082513432

to:

Bonaventure Akinlosotu

12/09/2010 09:34 AM

Show Details

Dear BA, we will be there. Attending for LoradoChem will be Dennis Steadman, Alex Kaufman, and me. See you a bit before 2 PM. Dave

APPLICATION TO REGISTER LC-2010-1 FIPRONIL FOR DOGS
FOR CONTROL OF FLEAS, TICKS AND CHEWING LICE

OPP Decision Number: D-429489

SUPPLEMENTAL SUBMISSION

ADDITION OF ALTERNATE SOURCE OF ACTIVE INGREDIENT

End-Use Product
EPA File Symbol 86230-E

VOLUME 86230-E-AS-1
ADMINISTRATIVE MATERIALS, CORRESPONDENCE, APPLICATION AND CONFIDENTIAL
STATEMENT OF FORMULA

DATA REQUIREMENTS
40 CFR 152.50

AUTHOR
Iain Weatherston, Ph.D.

DATE COMPLETED
December 7, 2010

SPONSOR
LORADO CHEM, Inc.
Cira Centre, 12th Floor
2929 Arch Street, Philadelphia, PA 16104-2891

SUBMITTED BY
Technology Sciences Group Inc.
4061 North 156th Drive Goodyear, AZ 85395

CONFIDENTIALITY CLAIMS

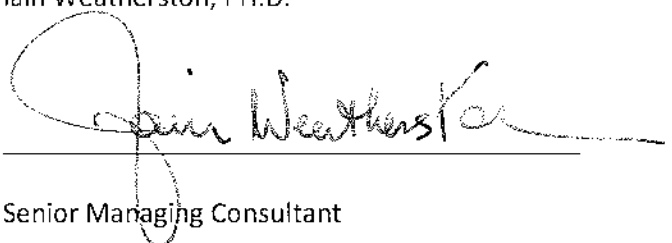
STATEMENT OF DATA CONFIDENTIALITY

Information claimed confidential on the basis of its falling within the scope of FIFRA § 10 (d)(1) [A], [B] or [C] has been removed to a confidential attachment and is cited by a cross-reference number in the body of the text.

COMPANY: LoradoChem Inc.

AGENT: Iain Weatherston, PH.D.

SIGNATURE:

A handwritten signature in black ink, appearing to read "Iain Weatherston", is written over a horizontal line. The signature is fluid and cursive.

TITLE: Senior Managing Consultant

DATE: December 7, 2010

GOOD LABORATORY PRACTICES STATEMENT

The purpose and scope of this report **DO NOT FALL UNDER** the requirements of 40 CFR 160.

CONTENTS

CONFIDENTIALITY CLAIMS	2.
GOOD LABORATORY PRACTICES STATEMENT	3.
CONTENTS	4.
LETTER OF INTRODUCTION	5.
APPLICATION FOR PESTICIDE REGISTRATION [Form 8570-1]	7.
PLACE HOLDER PAGE	8.
FORMULATOR'S EXEMPTION STATEMENT [Form 8570-27]	10.
DATA MATRIX [Form 9570-35]	11.
CONFIDENTIAL ATTACHMENT	
COVER	1.
CROSS REFERENCE PAGE	2.
CONFIDENTIAL STATEMENT OF FORMULA	3.

Richard Gebken
Product Manager, Team 10
U.S. EPA – OPP – RD – IB
One Potomac Yard
2777 South Crystal Drive
ARLINGTON, VA 22202

December 7, 2010

SUBJECT: Supplemental Submission
Addition of Alternate Source of Active Ingredient to the Registration
Package for LC-2010-2 FIPRONIL FOR DOGS

COMPANY: LoradoChem Inc., Cira Centre 12th Floor, 2929 Arch Street, Philadelphia,
PA 16104-2891.

CONTACT: Iain Weatherston, Ph.D., Technology Sciences Group Inc., 4061 North
156th Drive, Goodyear, AZ 85395. [623-535-4060]
iweatherston@tsgusa.com.

PRODUCT: LC-2010-2 FIPRONIL FOR DOGS [86230-E]

OPP DECISION NUMBER: D-429489

Dear Mr. Gebken:

As agent for, and on behalf of LoradoChem Inc., I submit for expedited review and approval, as decided at the November 22, 2010 meeting with the Registration Division Director, Associate Director, OGC attorney and the Branch Chiefs of IB and TRB, an application to add an alternate source of technical fipronil to the current pending registration for the subject product.

In addition to this letter, this Volume 86230-E-AS-1 contains:-

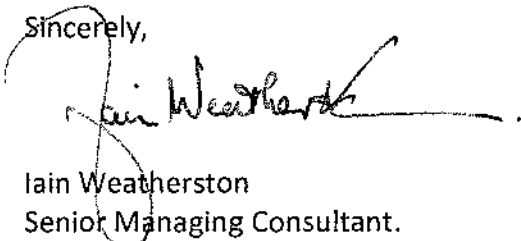
- A fully executed Application for Pesticide Registration [Form 8570-1]
- Formulators Exemption Statement [Form 8570-27]
- Data matrix [Form 8570-35]
- Confidential Statement of Formula [8570-4]

There is no label included, since the change of source of technical active ingredient does not impact the labeling.

In addition to the Administrative volume, the submission also includes an abbreviated product chemistry volume, Volume 86230-E-AS-2 as requested in a telephone call on Friday December 3, 2010 by Dan Kenny after consulting with Shyam Mathur.

Should you require any further information, or have any questions, please do not hesitate to contact me by e-mail at iweatherston@tsgusa.com or by telephone at 623-535-4060.

Sincerely,


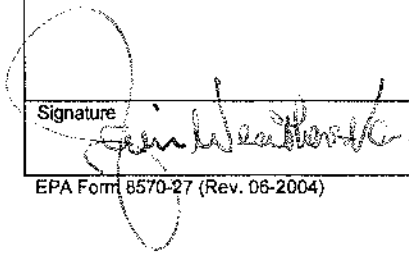
A handwritten signature in black ink, appearing to read "Iain Weatherston", with a long horizontal line extending to the right.

Iain Weatherston
Senior Managing Consultant.
Agent to LoradoChem Inc.

PLACE HOLDER PAGE

CROSS-REFERENCE NUMBER	[1]
DELETED PAGE:	Immediately following this page
PAGE DELETED:	9
REASON FOR DELETION:	Confidential Statement of Formula
FIFRA REFERENCE:	§ 10 (d)(1) (c)

Form approved. OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.

		
<p>United States Environmental Protection Agency Washington, DC 20460 Formulator's Exemption Statement (40 CFR 152.85)</p>		
Applicant's Name and Address LoradoChem, Inc., Cira Centre 12th Floor, 2929 Arch Street, Philadelphia, PA 16104-2891.	EPA File Symbol/Registration Number 86230-E	
	Product Name LC-2010-2 Fipronil for Dogs	
	Date of Confidential Statement of Formula (EPA Form 8570-4) 11/30/2010	
As an authorized representative of the applicant for registration of the product identified above, I certify that:		
(1) This product contains the following active ingredient(s): Fipronil		
(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).		
(3) Indicate by checking (A) or (B) below which paragraph applies: <input checked="" type="checkbox"/> (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1). OR <input type="checkbox"/> (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.		
(4) The following active ingredients in this product qualify for the formulator's exemption.		
Source		
Active Ingredient Fipronil [CAS# 120068-37-3]	Product Name Fipronil Technical	Registration Number 87650-R
Signature 	Name and Title Iain Weatherston /Sr. Manag. Cslt.	Date 11/30/2010

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
Copy 2 - Applicant copy

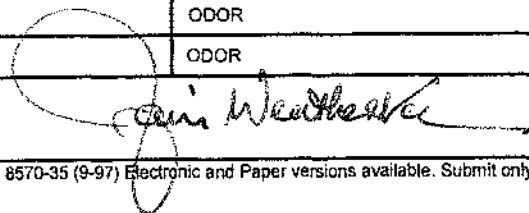


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 11/30/2010	EPA Reg No./File Symbol 86230-E	Page 1 of 3			
Applicant's/Registrant's Name & Address LORADO CHEM INC., CIRA CENTRE 12TH FLOOR, PHILADELPHIA, PA 16104-2891		Product LC-2010-2 FIPRONIL FOR DOGS			
Ingredient FIPRONIL					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	PRODUCT IDENTITY AND COMPOSITION		LORADO CHEM INC	OWN	V86230-E-AS-2
830.1550	PRODUCT IDENTITY AND COMPOSITION	48013001	LORADO CHEM INC	OWN	BRIDGE
830.1600	DESCRIPTION OF STARTING MATERIALS		LORADO CHEM INC	OWN	V86230-E-AS-2
830.1600	DESCRIPTION OF STARTING MATERIALS	48013001	LORADO CHEM INC	OWN	BRIDGE
830.1650	FORMULATION PROCESS		LORADO CHEM INC	OWN	V86230-E-AS-2
830.1650	FORMULATION PROCESS	48013001	LORADO CHEM INC	OWN	BRIDGE
830.1750	CERTIFIED LIMITS		LORADO CHEM INC	OWN	see CSF
830.1800	ENFORCEMENT ANALYTICAL METHOD		LORADO CHEM INC	OWN	V86230-E-AS-2
830.1800	ENFORCEMENT ANALYTICAL METHOD	48013001	LORADO CHEM INC	OWN	BRIDGE
830.6302	COLOR		LORADO CHEM INC	OWN	V86230-E-AS-2
830.6302	COLOR	48013001	LORADO CHEM INC	OWN	BRIDGE
830.6303	PHYSICAL STATE		LORADO CHEM INC	OWN	V86230-E-AS-2
830.6303	PHYSICAL STATE	48013001	LORADO CHEM INC	OWN	BRIDGE
830.6304	ODOR		LORADO CHEM INC	OWN	V86230-E-AS-2
830.6304	ODOR	48013001	LORADO CHEM	OWN	BRIDGE
Signature 			Name and Title Iain Weatherston Sr. Managing Consultant		Date 11/30/2010

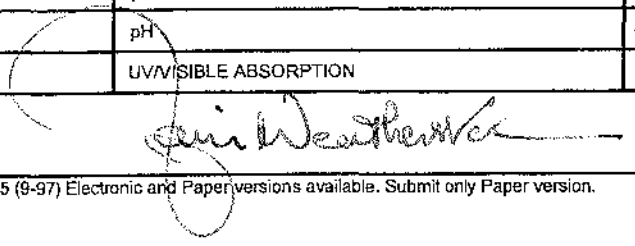


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 11/30/2010		EPA Reg No./File Symbol 86230-E		Page 2 of 3	
Applicant's/Registrant's Name & Address LORADO CHEM INC., CIRA CENTRE 12TH FLOOR, PHILADELPHIA, PA 16104-2891		Product LC-2010-2 FIPRONIL FOR DOGS			
Ingredient FIPRONIL					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6313	STABILITY TO TEMP., METALS & METAL IONS				NOT REQUIRED
830.6314	OXIDATION/REDUCTION POTENTIAL		LORADO CHEM INC	OWN	V86230-E-AS-2
830.6314	OXIDATION/REDUCTION POTENTIAL	48013001	LORADO CHEM INC	OWN	BRIDGE
830.6315	FLAMMABILITY		LORADO CHEM INC	OWN	V86230-E-AS-2
830.6315	FLAMMABILITY	48013001	LORADO CHEM INC	OWN	BRIDGE
830.6316	EXPLODABILITY		LORADO CHEM INC	OWN	V86230-E-AS-2
830.6316	EXPLODABILITY		LORADO CHEM INC.	OWN	BRIDGE
830.6317	STORAGE STABILITY		LORADO CHEM INC.	OWN	IN PROGRESS
830.6319	MISCIBILITY				NOT REQUIRED
830.6320	CORROSION CHARACTERISTICS		LORADO CHEM INC	OWN	IN PROGRESS
830.6321	DIELECTRIC BREAKDOWN CONSTANT		LORADO CHEM INC	OWN	V86230-R-AS-2
830.6321	DIELECTRIC BREAKDOWN CONSTANT	48013001	LORADO CHEM INC	OWN	BRIDGE
830.7000	pH		LORADO CHEM INC	OWN	V86230-R-AS-2
830.7000	pH	48013001	LORADO CHEM INC	OWN	BRIDGE
830.7050	UV/VISIBLE ABSORPTION		LORADO CHEM	OWN	NOT REQUIRED
Signature 			Name and Title Iain Weatherston Sr. Managing Consultant		Date 11/30/2010

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

LoradoChem Inc.
December 7, 2010
Registration of LC-2010-2; Fipronil for Dogs

Page 12 of 18

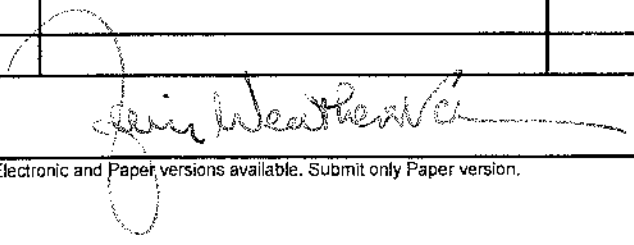


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 11/30/2010		EPA Reg No./File Symbol 86230-E		Page 3 of 3	
Applicant's/Registrant's Name & Address LORADOCEM INC., CIRA CENTRE 12TH FLOOR, PHILADELPHIA, PA 19104-2891		Product LC-2010-2 FIPRONIL FOR DOGS			
Ingredient FIPRONIL					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7100	VISCOSITY		LORADOCEM INC	OWN	V86230-E-AS-2
830.7100	VISCOSITY	48013001	LORADOCEM INC	OWN	BRIDGE
830.7200	MELTING POINT/RANGE				NOT REQUIRED
830.7220	BOILING POINT/RANGE				NOT REQUIRED
830.7300	DENSITY/BULK DENSITY/SPECIFIC GRAVITY		LORADOCEM INC	OWN	V86230-E-AS-2
830.7300	DENSITY/BULK DENSITY/SPECIFIC GRAVITY	48013001	LORADOCEM INC	OWN	BRIDGE
830.7373	DISSOCIATION CONSTANT				NOT REQUIRED
830.7550/60/70	PARTITION COEFFICIENT				NOT REQUIRED
830.7840/60	WATER SOLUBILITY				NOT REQUIRED
830.7950	VAPOR PRESSURE				NOT REQUIRED
ALL OTHER GUIDELINE	REQUIREMENTS ARE SATISFIED BY THE CITE-ALL	METHOD OF	DATA SUPPORT AND THE LIST OF		
COMPANIES SENT OFFER-TO-PAY	LETTERS IS BRIDGED FROM THE LIST GIVEN IN THE	DOCUMENT	WITH MRID 48013000		
Signature 			Name and Title Iain Weatherston Sr. Managing Consultant		Date 11/30/2010

TRANSMITTAL DOCUMENT

NAME & ADDRESS OF APPLICANT:

LoradoChem Inc.
Cira Centre, 12th Floor
2929 Arch Street, Philadelphia, PA 16104-2891

REGULATORY ACTION INSUPPORT OF WHICH THIS PACKAGE IS SUBMITTED:

Application to register LC-2010-2 Fipronil for Dogs
OPP Decision Number D-429489
SUPPLEMENTAL SUBMISSION
Alternate source of active ingredient

TRANSMITTAL DATE:

December 7, 2010

LIST OF SUBMITTED VOLUMES:

VOLUME 86230-E-AS-1
Administrative materials, correspondence, application and
confidential statement of formula

VOLUME 86230-E-AS-2
Supplemental Product Chemistry

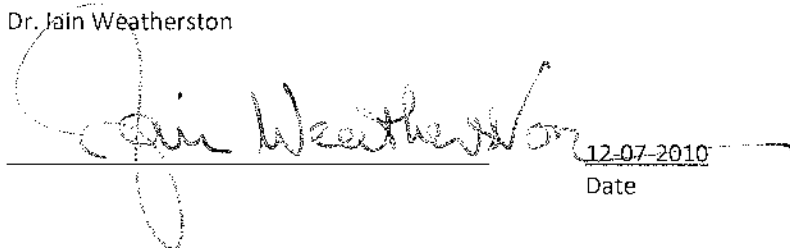
COMPANY NAME:

LoradoChem Inc.
Cira Centre, 12th Floor
2929 Arch Street, Philadelphia, PA 16104-2891

COMPANY AGENT:

Dr. Iain Weatherston

AGENT SIGNATURE:



12-07-2010
Date

COMPANY CONTACT:

Dr. Iain Weatherston
Technology Sciences Group Inc.
4061 North 156th Drive
Goodyear, AZ 85395

Telephone: 623-535-4060
Email: iweatherston@tsgusa.com

VEPRUST™
FIPRONIL FOR DOGS

3
APPLICATORS

for Dogs
23-44 lbs.

3
APPLICATORS

VEPRUST™
FIPRONIL FOR DOGS

3
APPLICATORS

for Dogs
23-44 lbs.

3
APPLICATORS

VEPRUST™
FIPRONIL FOR DOGS

3
APPLICATORS

for Dogs
23-44 lbs.

3
APPLICATORS

VEPRUST™
FIPRONIL FOR DOGS

3
APPLICATORS

for Dogs
23-44 lbs.

3
APPLICATORS

VEPRUST™
FIPRONIL FOR DOGS

3
APPLICATORS

for Dogs
23-44 lbs.

3
APPLICATORS

VEPRUST™
FIPRONIL FOR DOGS

3
APPLICATORS

for Dogs
23-44 lbs.

3
APPLICATORS

*VENDOR/SUPPLIER IS RESPONSIBLE FOR VERIFYING ALL TECHNICAL INFORMATION
DRUG FACTS, UPC CODES, ITEM CODES AND FINAL DIE LINES.

CBX	VEPRUST For Dogs Carton	PROCESS COLOR	MECHANICAL DEVELOPMENT LOG
<p>DATE: 01/11/2011</p> <p>DESIGNER: [Signature]</p> <p>DATE: 01/11/2011</p> <p>DESIGNER: [Signature]</p> <p>DATE: 01/11/2011</p> <p>DESIGNER: [Signature]</p>	<p>VEPRUST For Dogs Carton</p> <p>DATE: 01/11/2011</p> <p>DESIGNER: [Signature]</p> <p>DATE: 01/11/2011</p> <p>DESIGNER: [Signature]</p> <p>DATE: 01/11/2011</p> <p>DESIGNER: [Signature]</p>	<p>PROCESS COLOR</p> <p>DATE: 01/11/2011</p> <p>DESIGNER: [Signature]</p> <p>DATE: 01/11/2011</p> <p>DESIGNER: [Signature]</p> <p>DATE: 01/11/2011</p> <p>DESIGNER: [Signature]</p>	<p>MECHANICAL DEVELOPMENT LOG</p> <p>DATE: 01/11/2011</p> <p>DESIGNER: [Signature]</p> <p>DATE: 01/11/2011</p> <p>DESIGNER: [Signature]</p> <p>DATE: 01/11/2011</p> <p>DESIGNER: [Signature]</p>

Sublabel C: Labeling on the Child Resistant Package

Top of lidding foil: Dotted line with representation of a scissors

Company Name: FidoPharm

Product Name: VeTrust™ for Dogs

Graphic picture of the pipette

Instructions: **To Open Package:**
Cut across the top
as shown.
Peel down foil
completely before
removing pipette.

Species and amount: Dog 22 – 0.023 fl. oz.
or
Dog 44 – 0.045 fl. oz.
or
Dog 88 - 0.091 fl. oz.
or
Dog 132 – 0.136 fl.oz.

Lot number: Lot No: XXXX

Sublabel D: Labeling on the Pipette

Neck of pipette: Contains: fipronil (9.7%)

Body of pipette:

FidoPharm

0.023 fl. oz.

VeTrust™ for Dogs

For Dogs up to 22 lbs.

Keep out of reach of children

See full label for

Additional directions

Caution

EPA Reg. No 86230-E-85495

Or

FidoPharm

0.045 fl. oz.

VeTrust™ for Dogs

For Dogs up to 23-44 lbs.

Keep out of reach of children

See full label for

Additional directions

Caution

EPA Reg. No 86230-E-85495

Or

FidoPharm

0.091 fl. oz.

VeTrust™ for Dogs

For Dogs up to 45-88 lbs.

Keep out of reach of children

See full label for

Additional directions

Caution

EPA Reg. No 86230-E-85495

Or

FidoPharm

0.136 fl. oz.

VeTrust™ for Dogs

For Dogs up to 89-132 lbs.

Keep out of reach of children

See full label for

Additional directions

Caution

EPA Reg. No 86230-E-85495



Remove the adhesive backing and attach to your refrigerator door.

***VENDOR/SUPPLIER IS RESPONSIBLE FOR VERIFYING ALL TECHNICAL INFORMATION, DRUG FACTS, UPC CODES, ITEM CODES AND FINAL DIE LINES.**

CEX 12/15/15 12/15/15 12/15/15 12/15/15 12/15/15	VeTrust For Dogs Compliance Card File: 12/15/15 Job No: 12/15/15 Version: 12/15/15 Date: 12/15/15 Author: 12/15/15	PROCESS COLORS 12/15/15 12/15/15 12/15/15 12/15/15	MECHANICAL DEVELOPMENT LOG <table border="1"> <thead> <tr> <th>DATE</th> <th>DESCRIPTION</th> <th>BY</th> <th>APPROVED</th> <th>DATE</th> </tr> </thead> <tbody> <tr> <td>12/15/15</td> <td>Developed first design</td> <td>12/15/15</td> <td></td> <td></td> </tr> <tr> <td>12/15/15</td> <td>Added labels</td> <td>12/15/15</td> <td></td> <td></td> </tr> <tr> <td>12/15/15</td> <td>Added color to the design</td> <td>12/15/15</td> <td></td> <td></td> </tr> </tbody> </table>	DATE	DESCRIPTION	BY	APPROVED	DATE	12/15/15	Developed first design	12/15/15			12/15/15	Added labels	12/15/15			12/15/15	Added color to the design	12/15/15			CEX APPROVALS <table border="1"> <thead> <tr> <th>DATE</th> <th>BY</th> <th>APPROVED</th> </tr> </thead> <tbody> <tr> <td>12/15/15</td> <td></td> <td></td> </tr> <tr> <td>12/15/15</td> <td></td> <td></td> </tr> <tr> <td>12/15/15</td> <td></td> <td></td> </tr> </tbody> </table>	DATE	BY	APPROVED	12/15/15			12/15/15			12/15/15		
DATE	DESCRIPTION	BY	APPROVED	DATE																																
12/15/15	Developed first design	12/15/15																																		
12/15/15	Added labels	12/15/15																																		
12/15/15	Added color to the design	12/15/15																																		
DATE	BY	APPROVED																																		
12/15/15																																				
12/15/15																																				
12/15/15																																				

FW: COMPLIANCE CARDS

David Petrick

to:

Bonaventure Akinlosotu

12/07/2010 01:02 PM

Cc:

Richard Gebken, Marion Johnson

Show Details

Dear BA,

Here is the final email.

These represent the final proposed 4 compliance cards we would like to include in the cartons.

There is information to appear on the back of the CR package/blister, and the back of the pipettes. The wording on both of these has not changed from the original submissions back in late February and early March. If you want me to send this along, just let me know and I will do so.

I have also included the note I sent to you that outlined our thoughts on why our proposals would be in compliance with EPA directives and guidance.

Please let me know if you need anything else, or need additional clarity.

You can reach me at 267.757.3613 or on my mobile at 908-251-3432.

Thanks again for all the help. Settling on the labeling will really be a huge help to us!

Best Regards,

Dave

David M. Petrick, VMD, JD

Vice President Regulatory Affairs

Velcera, Inc. - Breaking through to improve pet medicine

777 Township Line Road

Suite 170

Yardley, PA 19067-5508

Telephone: 267-757-3600

FAX: 267-757-3601

email address: dpetrick@velcera.com

Confidentiality Notice: This email transmission (and the attachments accompanying it) may contain confidential information belonging to the sender which is protected. The information is intended only for the intended recipient(s). If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or taking of any action in reliance of this information is prohibited. If you have received this transmission in error, please notify the sender immediately by reply email and destroy all copies of this transmission.


From: Alex Kaufman

Sent: Thursday, November 11, 2010 10:06 AM

To: Iain Weatherston

Cc: David Petrick; davidpetrick@comcast.net; Dennis Steadman

Subject: COMPLIANCE CARDS

 Logo at 25%



RE: FW: Labeling

David Petrick to: Bonaventure Akinlosotu

12/07/2010 05:14 PM

Cc: "Iain Weatherston", Marion Johnson, Richard Gebken

Dear Bonaventure,

Attached are four files for your inclusion in the labeling for the 4 LoradoChem products, 86230-R, 86230-E, 86230-G, and 86230-U. These will replace the original "Master Labeling" originally filed, and do represent wording for each size of product to be presented for sale. These are Text versions, as originally submitted

I am including here Sublabels C and D (as described in the original applications) for each of the products. These are to be the final draft versions LoradoChem is submitting for review and approval. Consistent with the plate labels that you have, these use FidoPharm in the labeling.

Products 86230-R, the mono cat, and 86230-E, the combo cat have the information presented for both the CR package and the pipette. There is only one size for each of these products.

Products 86230-E, the mono dog, and 86230-U, the combo dog also have information presented for the CR package and the pipette. Because there are 4 sizes proposed, the Sublabels C and D show alternate wording to accommodate the various sizes for the Dog, up to 22 lbs., 23-44 lbs., 45-88 lbs., and 89-132 lbs.

Please let me know if you have any additional questions.

David M. Petrick, VMD, JD
Vice President Regulatory Affairs
Velcera, Inc. - Breaking through to improve pet medicine
777 Township Line Road
Suite 170
Yardley, PA 19067-5508
Telephone: 267-757-3600
FAX: 267-757-3601
email address: dpetrick@velcera.com

Confidentiality Notice: This email transmission (and the attachments accompanying it) may contain confidential information belonging to the sender which is protected. The information is intended only for the intended recipient(s). If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or taking of any action in reliance of this information is prohibited. If you have received this transmission in error, please notify the sender immediately by reply email and destroy all copies of this transmission.

-----Original Message-----

From: Akinlosotu.Bonaventure@epamail.epa.gov [mailto:Akinlosotu.Bonaventure@epamail.epa.gov]
Sent: Tuesday, December 07, 2010 3:21 PM
To: David Petrick
Cc: Iain Weatherston; Johnson.Marion@epamail.epa.gov; Gebken.Richard@epamail.epa.gov
Subject: Re: FW: Labeling

Hi Dave:

Since the "wording for the back of the CRP blister and the back of the pipette" are part of the "Master Labeling", I suggest you re-send the exact wording. Per my earlier conversation with you, we have several versions of the different components of the labeling.
Thx, B.A

Bonaventure Akinlosotu, PhD
EPS - Regulatory Scientist
U.S. Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
OPP/RD (Mail Code: 7505P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Physical Address
One Potomac Yard
2777 Crystal Dr.
Arlington, VA 22202

703-605-0653
akinlosotu.bonaventure@epa.gov

This email may contain material that is confidential, privileged, and/or work product for the sole use of the intended recipient. Any review, reliance, distribution by others, or forwarding without express permission is strictly prohibited. If you are not the intended recipient please contact the sender and delete all copies.

From: "David Petrick" <dpetrick@velcera.com>
To: Bonaventure Akinlosotu/DC/USEPA/US@EPA
Cc: Richard Gebken/DC/USEPA/US@EPA, Marion Johnson/DC/USEPA/US@EPA, "Iain Weatherston" <IWeatherston@TSGUSA.COM>
Date: 12/07/2010 02:59 PM
Subject: FW: Labeling

Dear Bonaventure,

I did want to remind you that the wording originally submitted for the back of the CRP blister and the back of the pipette still are to be used in the labeling for the 4 products. This is as I stated in the last of the three emails sent to you earlier. If you want copies of those provided as well, just let me know and I will email them to you.

Best Regards,

Dave

David M. Petrick, VMD, JD
Vice President Regulatory Affairs
Velcera, Inc. - Breaking through to improve pet medicine
777 Township Line Road
Suite 170
Yardley, PA 19067-5508
Telephone: 267-757-3600
FAX: 267-757-3601
email address: dpetrick@velcera.com

Confidentiality Notice: This email transmission (and the attachments accompanying it) may contain confidential information belonging to the sender which is protected. The information is intended only for the intended recipient(s). If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or taking of any action in reliance of this information is prohibited. If you have received this transmission in error, please notify the sender immediately by reply email and destroy all copies of this transmission.

From: David Petrick
Sent: Tuesday, December 07, 2010 2:48 PM
To: Akinlosotu.Bonaventure@epamail.epa.gov
Cc: 'gebken.richard@epa.gov'; Johnson.Marion@epamail.epa.gov; 'Iain Weatherston'
Subject: Labeling

Dear Bonaventure,

As you requested in your voicemail, this is to confirm that the emails sent to you earlier today represent our final revisions in our proposed labeling for the 4 LoradoChem products. They are intended to replace the original Master Labels that were initially submitted, as well as all other labeling that was submitted up to this point.

Please let me know if you need further clarification.

Best Regards,


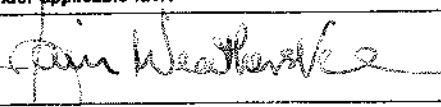
Dave

David M. Petrick, VMD, JD
Vice President Regulatory Affairs
Velcera, Inc. - Breaking through to improve pet medicine
777 Township Line Road
Suite 170
Yardley, PA 19067-5508
Telephone: 267-757-3600
FAX: 267-757-3601
email address: dpetrick@velcera.com

Confidentiality Notice: This email transmission (and the attachments accompanying it) may contain confidential information belonging to the sender which is protected. The information is intended only for the intended recipient(s). If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or taking of any action in reliance of this information is prohibited. If you have received this transmission in error, please notify the sender immediately by reply email and destroy all copies of this transmission.

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95

		United States Environmental Protection Agency Washington, DC 20460		<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I					
1. Company/Product Number 86230-E		2. EPA Product Manager RICHARD GEBKEN		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
4. Company/Product (Name) LORADO CHEM INC. / LC-2010-2 FIPRONIL FOR DOGS		PM# 10			
5. Name and Address of Applicant (Include ZIP Code) LoradoChem Inc., Cira Centre, 12th Floor, 2929 Arch St., Philadelphia, PA 16104-2871 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____			
Section - II					
<input checked="" type="checkbox"/> Amendment - Explain below.					
<input type="checkbox"/> Resubmission in response to Agency letter dated _____					
<input type="checkbox"/> Notification - Explain below.					
<input type="checkbox"/> Final printed labels in response to Agency letter dated _____					
<input type="checkbox"/> "Me Too" Application.					
<input type="checkbox"/> Other - Explain below.					
Explanation: Use additional page(s) if necessary. (For section I and Section II.) Submission of alternate source of fipronil active ingredient to expedite the end-use product approval as agreed to at the November 22, 2010 between the applicant and Lois Rossi.					
Section - III					
1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. _____ No. per container _____	If "Yes" Package wgt _____ No. per container _____		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container _____		5. Location of Label Directions <input type="checkbox"/> _____	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			
Section - IV					
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name IAIN WEATHERSTON		Title SENIOR MANAGING CONSULTANT		Telephone No. (Include Area Code) 623-535-4087	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title SENIOR MANAGING CONSULTANT			
4. Typed Name IAIN WEATHERSTON		5. Date November 30, 2010			

APPLICATION TO REGISTER LC-2010-2 FIPRONIL FOR DOGS
FOR CONTROL OF FLEAS, TICKS AND CHEWING LICE

ADDITION OF ALTERNATE SOURCE OF ACTIVE INGREDIENT

End-Use Product
EPA File Symbol 86230-E

VOLUME 86230-E-AS-1CA

CONFIDENTIAL ATTACHMENT

DATA REQUIREMENTS
40 CFR 152.50

AUTHOR
Iain Weatherston, Ph.D.

DATE COMPLETED
November 30, 2010

SPONSOR
LORADOCHEM, Inc.
Cira Centre, 12th Floor
2929 Arch Street, Philadelphia, PA 16104-2891

SUBMITTED BY
Technology Sciences Group Inc.
4061 North 156th Drive Goodyear, AZ 85395

CROSS-REFERENCE PAGE

CROSS-REFERENCE NUMBER	[1]
DELETED PAGE:	Immediately following this page
PAGE DELETED:	9
REASON FOR DELETION:	Confidential Statement of Formula
FIFRA REFERENCE:	§ 10 (d)(1) (c)

FW: CARTON Labeling Mono and Combo
David Petrick
to:
Bonaventure Akinlosotu
12/07/2010 12:49 PM
Cc:
Richard Gebken, Marion Johnson
Show Details

Dear BA,

Thanks for the call.

I am sending three emails to you with the materials from Alex which were sent to Iain on November 11th. These copies represent our last drafts for EPA review and consideration.

This first email has the cartons/boxes. These are the boxes for the various mono and combo products.

Two more will follow, to be sure there will be no problem in receiving them.

Dave

David M. Petrick, VMD, JD
Vice President Regulatory Affairs
Velcera, Inc. - Breaking through to improve pet medicine
777 Township Line Road
Suite 170
Yardley, PA 19067-5508
Telephone: 267-757-3600
FAX: 267-757-3601
email address: dpetrick@velcera.com

Confidentiality Notice: This email transmission (and the attachments accompanying it) may contain confidential information belonging to the sender which is protected. The information is intended only for the intended recipient(s). If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or taking of any action in reliance of this information is prohibited. If you have received this transmission in error, please notify the sender immediately by reply email and destroy all copies of this transmission.

From: Alex Kaufman
Sent: Thursday, November 11, 2010 9:57 AM
To: Iain Weatherston
Cc: davidpetrick@comcast.net; David Petrick; Dennis Steadman
Subject: CARTON Labeling Mono and Combo

Iain:

All files non-zipped.

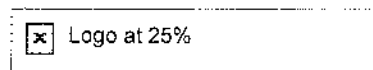
Sending:

First e-mail CARTONS
Second email INSERTS
Third e-mail COMPLIANCE CARDS

Call with any questions

Regards

Alex



Meeting with Lorado Chem

11/22/10

<u>Name</u>	<u>Organization</u>	<u>phone</u>
Jeff Herndon	EPA/RD	(703) 305-6362
Bob Rossi	EPA/RD	703-308-8162
DAVE PETRICK	Lorado Chem	267-757-3613
Alex Kaufman	Lorado Chem	
Stan Abramson	Arent Fox	202-857-8935
MARION J. JOHNSON, JR.	EPA/RD/IB	703 305-6788
Scott Garrison	EPA/OGC	202 564-4047
Rosalind L Gross	OPP/RD/TRB	703 308-7368
Richard Gebken	OPP/RD/IB	703-305-6701
Breann Hanson	OPP/RD/TRB	703 305 6891
DAN KENNY	OPP/RD/TRB	703-305-7546
DENNIS STEADMAN	LORADO Chem	267-757-3600

LoradoChem
Iain Weatherston
to:
Marion Johnson
11/19/2010 12:00 PM
Cc:
Richard Gebken, davidpetrick
Show Details

Marion:

This is a follow-up to our voicemail exchange of yesterday (actually your call was on Wednesday) and my call to you a few moments ago. Although I understand the workings of the PRIA categories and the PRIA approval date, neither I nor the client knew that the dates were "controlled by computer" and that the failure of another date being entered would automatically move the products out of the queue. Since the PRIA date is "in dispute" and the subject of a meeting between the client and the Director of OPP (at which you will be present) – the offering of a renegotiated PRIA date until after the meeting seemed appropriate.

If you believe that we should not wait until after the meeting, and it is not too late today – then I have been instructed to accept the February 17, 2011 as the renegotiated PRIA date provide there is an understanding that this date is not satisfactory to LoradoChem and that another PRIA date renegotiation will take place after the Monday meeting with Lois.

Regards,
Iain

LORADOCHEM PRODUCTS RENEGOTIATED PRIA DATE

Iain Weatherston

to:

Richard Gebken

11/17/2010 11:59 AM

Cc:

Marion Johnson, Dan Kenny, Bonaventure Akinlosotu

Show Details

Richard:

Regarding the date of November 17, 2010 as the PRIA date for the four LoradoChem products, this came as a surprise to me because although you offered this date in a telephone call with me on September 3 and accepted the same day by LoradoChem, however, at the September 14 meeting you stated that the November 17" date was a "fuzzy" date because when you offered it you were not aware of the CRP issues, and the November 17 date was now "off the table." Moreover, in a letter dated October 8, to Diane Isbell in the Director's office (copied to Debbie McCall and Marion Johnson) I did propose a date of November 30 to which I have not received a reply.

At this time my client does not wish to accept February 17, 2011 as a renegotiated PRIA date since they are meeting with Lois Rossi on Monday November 22. Amongst the agenda items for this meeting are the Agency's handling of the CRP issues, a commitment regarding the product labeling, the issue of technical approvals and the negotiation of a solid PRIA date. Very shortly after the Monday meeting I will write to you on behalf of LoradoChem proposing a new PRIA date that has come out of discussions at the meeting.

My client remains committed to working with the Agency to reach a satisfactory resolution of the issues affecting their application for registration.

Regards,

Iain

Product Performance Data Evaluation Report
By Kevin J. Sweeney, Senior Entomologist, Insecticides Branch

Kevin J. Sweeney
11-15-10

Date: November 15, 2010

Reviewer: Bonaventure Akinlosotu

Product: LC-2010-2 Plus Fipronil for Dogs

EPA Registration No.: 86230-2 (E)

PM: Richard Gebken, PM 10

Action: R310

Decision: 429489

DP No: 383777

OPPTS Guideline: 810.3300

Insecticides: 9.7% fipronil (PC code 129121)

App rate: apply in accordance with dog weight class ranges listed on label.

Formulation: RTU spot-on

GLP studies: studies were cited from a similar product – EPA Reg. No. 65331-3

Pests: fleas, ticks, sarcoptic mange (scabies) mite, chewing lice

Use pattern/application rate: Spot-on to dog. Apply to one-spot between shoulders.

Request: Label review and data citation to add the claim” Kills Mosquitoes”.

Entomologist’s Recommendation:

1. The cited product and “cite-all” method to fulfill the product performance data requirement are acceptable and support the addition of the claim: “Kills Mosquitoes”.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



November 2, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

TECHNOLOGY SCIENCES GROUP, INC.
LORADO CHEM, INC.
CIRCA CENTRE, 12TH FLOOR
4061 NORTH 156TH DRIVE
GOODYEAR, AZ 85338-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 28-OCT-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Technology Sciences Group Inc.
 Western Division
 4061 North 156th Drive
 Goodyear, AZ 85338
 Phone: (623) 535-4060
 E-Mail: iweatherston@tsgusa.com

Iain Weatherston, Ph.D.
 Senior Managing Consultant



October 1, 2010

MB: Resubmitted 10/28/2010

Richard Gebken
 Product Manager 10,
 U.S. EPA – OPP – RD – IB
 One Potomac Yard
 2777 South Crystal Drive
 Arlington, VA 22202

SUBJECT: Resubmission of CRP Senior Panel Data in support of the registration of LC-2010-1 (Fipronil for Cats); LC-2010-2 (Fipronil for Dogs); LC-2010-3 (Fipronil & S-Methoprene for Cats) and LC-2010-4 (Fipronil & S-Methoprene for Dogs).
 Submission of CRP Senior Panel Data and Child Panel Data in support of the registration of LC-2010-2 (Fipronil for Dogs) and LC-2010-4 (Fipronil & S-Methoprene for Dogs).

COMPANY: LoradoChem, Inc., Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, PA 18106-2891.

CONTACT: Iain Weatherston, Ph.D., Technology Sciences Group Inc.
 (contact information as per letterhead)

PRODUCTS: File Symbol 86230-R (LC-2010-1 Fipronil for Cats)
 86230-E (LC-2010-2 Fipronil for Dogs)
 86230-G (LC-2010-3 Fipronil & S-Methoprene for Cats)
 86230-U (LC-2010-4 Fipronil & S-Methoprene for Dogs)

Dear Mr. Gebken:

LoradoChem Inc., wish to thank you again for the meeting held on September 14, 2010 to discuss issues with the previously submitted CRP data and the need to submit both child and senior panel data for the 0.023 fl.oz. dog product pipettes.

In the accompanying submissions we will address each study review as discussed by EPA on September 14, 2010, using the MRID number identified in the review. We have approached the reply in the following way. Where EPA identified particular raw data sheets where a clarifying photograph was requested, we have placed a copy of the photograph with the expanded description directly behind the raw data sheet. In addition, each of the added photographs has been included in an Appendix to the full study report. The photographs are all on separate pages and are identified by the package number from the raw data sheet. Other specifics will be addressed in the summary for each MRID Number from the EPA reviews.

1. MRID 480057-03 (Study Number GLM 10052): The four packages which were deemed to be inconclusive; packages 18, 46, 45, and 80; now have an explanatory page and a photograph of the opened packages included in the report. In addition, as explained above, these 4 explanatory pages and photographs are included as Appendix 1 at the end of the report for the convenience of review. There is no change to the data analysis or to the final report.

2. MRID 480130-02 (Study Number GLM 10058): The four packages which were deemed to be inconclusive; packages 57, 71, 86, and 99; now have an explanatory page and a photograph of the opened packages included in the report. In addition, these 4 explanatory pages and photographs are included as Appendix 1. There is no change to the data analysis or to the final report.

3. MRID 480130-03 (Study Number GLM 10053): EPA indicated that there were 75 pages of raw data sheets missing in the copy that was presented to the reviewer. We apologize for this error in copying, and we have made certain that the omitted pages are included now. In addition, there was an error identified in the review concerning a calculation error for a 54 year old female that was reported as 55. A new subject was added and a new data sheet was added to the report directly behind the original one. This is related to Package 36. The new subject data sheet is so notated. In addition, based on the meeting of September 14, 2010, and the reviews of the other studies, any raw data sheets that had a comment that might be viewed as "inclusive" now have explanatory pages and photographs added directly behind the raw data sheet. These explanatory pages and photographs are also included as Appendix 1 at the end of the report.

There is no change to the data analysis since the new subject was also a "pass," but a new report has been included to account for the error made in the age distribution.

4. MRID 480130-04 (Study Number GLM 10057): The six packages which were deemed to be inconclusive; packages 1, 15, 44, 48, 54 and 80; now have an explanatory page and a photograph of the opened packages included in the report. In addition, these 6 explanatory pages and photographs are included as Appendix 1. There is no change to the data analysis or to the final report.

5. MRID 480132-03 (Study Number GLM 29081): The four packages which were deemed to be inconclusive; packages 14, 64, 80, and 83; now have an explanatory page and a photograph of the opened packages included in the report. In addition, these 4 explanatory pages and photographs are included as Appendix 1. There is no change to the data analysis or to the final report.

6. MRID 480131-03 (Study Number GLM 29087): The eight packages which were deemed to be inconclusive; packages 14, 20, 24, 26, 43, 82, 87, and 92; now have an explanatory page and a photograph of the opened packages included in the report. In addition, these 8 explanatory pages and photographs are included as Appendix 1. There is no change to the data analysis or to the final report.

7. MRID 480131-04 (Study Number GLM 29088): The three packages which were deemed to be inconclusive; packages 27, 52, and 77; now have an explanatory page and a photograph of the opened packages included in the report. An additional observation was made concerning a remark on the raw data sheet that stated, "water leaking into cavity before she opened," and a

further clarification has been provided. In addition, these 4 explanatory pages and photographs are included as Appendix 1. There is no change to the data analysis or to the final report.

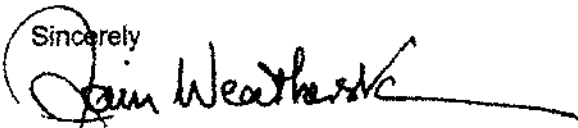
8. MRID 480131-02 (Study Number GLM 29086): The four packages which were deemed to be inconclusive; packages 27, 39, 62, and 95; now have an explanatory page and a photograph of the opened packages included in the report. In addition, these 4 explanatory pages and photographs are included as Appendix 1. There is no change to the data analysis or to the final report.

As noted in the EPA review, data had not been provided on the smallest pipette size with the second fill volume which will be used for the Smallest Dog presentations – referred to as Dog 22, since this package size is to be used for dogs up to 22 pounds in body weight. As requested by EPA, studies have been conducted for children and senior adult panels for both the teal and the purple color pipettes. These four study reports and raw data sheets are included in this submission as well. These are GLM Studies GLM 10230, Teal Dog 22 3-cards, and GLM 10177, Purple Dog 22 3-cards. Please note, following the practice used in the 8 previously submitted studies, if the raw data sheet identified a pass that had similar results as before that might cause them to be classed as "inconclusive," a photograph is included directly behind the raw data sheet. These photograph pages were not included as an Appendix since these reports have not been seen before. The results in these child and senior adult panels as expected, are similar to the results seen in the first set of 16 studies.

Please be advised that as requested in the review and at the meeting, the storage section of the labels for the products will be amended to read, "Store unused application pipettes in the original unopened child-resistant container and..." as appropriate. In a subsequent meeting at EPA on September 23, 2010, additional comments were made concerning the labels for the various products. As several changes are being discussed, amended labels may be filed shortly. In any event, copies of the labels will be provided to insure the CRP reviewer can see the changes as requested have been made.

LoradoChem has made a good faith effort to work with the Agency to resolve and clarify in a most expeditious manner the stated issues with the initial CRP submissions. The company trusts that the Agency will reciprocate in negotiating a new PRIA date in the month of November 2010.

Sincerely



Iain Weatherston
Agent for LoradoChem

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

LoradoChem, Inc.
Cira Centre, 12th Floor, 2929 Arch Street
Philadelphia, PA 18104-2891

REGULATORY ACTION:

Submission of the supplemental information to support the registration of LC-2010-2 Fipronil for Dogs (EPA File Symbol: 86230-E).

TRANSMITTAL DATE:

October 1, 2010

LIST OF SUBMITTED STUDIES:

MRID NUMBER	VOLUME NUMBER	EPA STUDY TITLE	GUIDELINE NUMBER
48278901	86230-E-3-S	LC-2010-2 Fipronil for Dogs Child Resistant Packaging Testing Senior Panel Study No.: GLM 10058S	Non-guideline
48278902	86230-E-4-S	LC-2010-2 Fipronil for Dogs Child Resistant Packaging Testing Senior Panel Study No.: GLM 10053S	Non-guideline
48278903	86230-E-5-S	LC-2010-2 Fipronil for Dogs Child Resistant Packaging Testing Senior Panel Study No.: GLM 10057S	Non-guideline
48278904	86230-E-9	LC-2010-2 Fipronil for Dogs Child Resistant Packaging Testing Senior Panel Study No.: 10177S	Non-guideline
48278905	86230-E-10	LC-2010-2 Fipronil for Dogs Child Resistant Packaging Testing Child Panel Study No.: 10177C	Non-guideline

COMPANY NAME:

LoradoChem, Inc.

COMPANY OFFICIAL:



Iain Weatherston, Senior Regulatory Consultant

COMPANY CONTACT:

Iain Weatherston, Senior Regulatory Consultant
Technology Sciences Group, Inc.
4061 N 156th Drive
Goodyear, AZ 85395
(623) 535-4060

Technology Sciences Group Inc.
Western Division
4061 North 156th Drive
Goodyear, AZ 85338
Phone: (623) 535-4060
E-Mail: iweatherston@tsgusa.com

Iain Weatherston, Ph.D.
Senior Managing Consultant



October 8, 2010

Ms. Diane Isbell
Special Assistant
U.S. EPA – OPP – RD
One Potomac Yard
2777 South Crystal Drive,
ARLINGTON, VA 22202

Claimed confidential by submitter

COMPANY CONFIDENTIAL

Claimed confidential by submitter

COMPANY CONFIDENTIAL

Claimed confidential by submitter

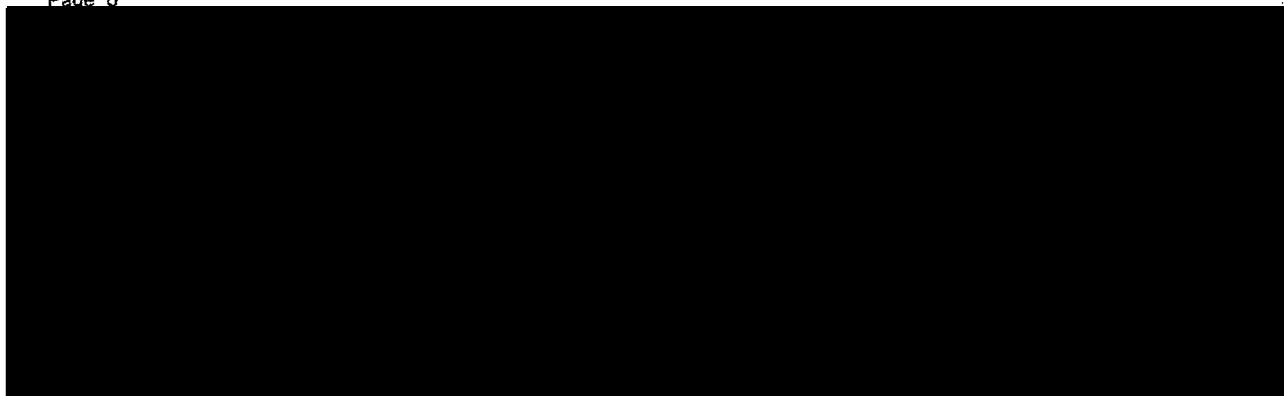
COMPANY CONFIDENTIAL

Claimed confidential by submitter

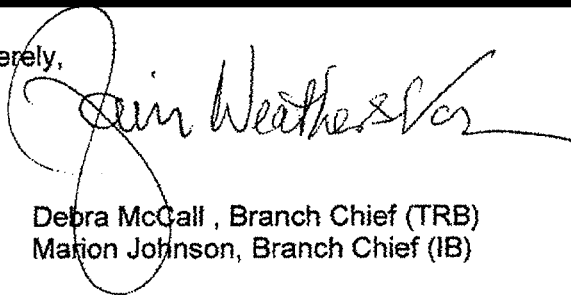
COMPANY CONFIDENTIAL

Claimed confidential by submitter

COMPANY CONFIDENTIAL



Sincerely,

A handwritten signature in black ink, appearing to read "Jim Weather". The signature is written in a cursive style and is positioned to the right of the word "Sincerely,".

cc: Debra McCall , Branch Chief (TRB)
Mation Johnson, Branch Chief (IB)

Claimed confidential by submitter

COMPANY CONFIDENTIAL



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 86230-E	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) LoradoChem Inc. / LC-2010-2 Fipronil for Dogs	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) LoradoChem Inc., Cira Centre 12th Floor, 3929 Arch Street, Philadelphia, PA 18104-2891 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Resubmission of CRP Senior Panel Data following various telephone calls, a letter and a meeting at the Agency on September 14, 2010.
Submission of CRP Child and Senior Panel Data for 0.023 fl. oz. pipettes following the meeting at the Agency on September 14, 2010.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Iain Weatherston		Title Senior Regulatory Consultant		Telephone No. (Include Area Code) (623)-535-4063	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Senior Regulatory Consultant			
4. Typed Name Iain Weatherston		5. Date October 1, 2010			

LoradoChem, Inc.

Circa Center, 12th Floor

2929 Arch Street

Philadelphia, PA 18104-2891

Richard Gebken
Product Manager #10
U.S. EPA –OPP – RD – IB
One Potomac Yard
2777 S. Crystal Drive,
Arlington VA 22202

October 18, 2010

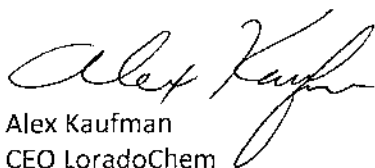
SUBJECT: Letter of authorization from LoradoChem Inc., in support of the registration of Fipronil Technical [89731-R] submitted by Raymat Materials Inc.

Dear Mr. Gebken:

As agent for, and on behalf of LoradoChem Inc., I am writing to authorize the U.S. Environmental Protection Agency to review the product chemistry data sponsored by LoradoChem in support of the registration of Fipronil Technical [89731-R] submitted by Raymat Materials Inc.

This letter of authorization is only qualified to the extent that (1) the applicant or any other person, except the Agency, shall not have access to the data unless specifically authorized in writing by LoradoChem Inc., or in the opinion of the Agency, it is required in judicial or administrative proceedings, (2) this authorization shall not be construed as authorization to use or consider these data directly or indirectly, in support of any subsequent application, and (3) this authorization shall not be transferred by Raymat Materials Inc., in any manner whatsoever without the express prior consent of LoradoChem Inc.

Sincerely,


Alex Kaufman
CEO LoradoChem

*will withdraw this
letter, per discussion
of 12/21/2010 mtg.*



86230-E

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 14, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

TECHNOLOGY SCIENCES GROUP, INC.
LORADO CHEM, INC.
CIRCA CENTRE, 12TH FLOOR
4061 NORTH 156TH DRIVE
GOODYEAR, AZ 85338-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 01-OCT-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

Rejected Study [01]:

* Your Statement of No Data Confidentiality Claims is contradicted by the marking(s) on page(s) 32 and 33 of the study. If you do not intend to make Supplemental Claims of Data Confidentiality you can explicitly override these markings when you resubmit this study.

Rejected Study [02]:

* Your Statement of No Data Confidentiality Claims is contradicted by the marking(s) on page(s) 33 and 34 of the study. If you do not intend to make Supplemental Claims of Data Confidentiality you can explicitly override these markings when you resubmit this study.

Rejected Study [03]:

* Your Statement of No Data Confidentiality Claims is contradicted by the marking(s) on page(s) 31 and 32 of the study. If you do not intend to make Supplemental Claims of Data Confidentiality you can explicitly override these markings when you resubmit this study.

Rejected Study [04]:

* Your Statement of No Data Confidentiality Claims is contradicted by the marking(s) on page(s) 30 of the study. If you do not intend to make Supplemental Claims of Data Confidentiality you can explicitly override these markings when you resubmit this study.

Rejected Study [05]:

UNRESOLVED FIPRONIL ISSUES

Iain Weatherston

to:

Richard Gebken, Marion Johnson

10/04/2010 10:58 PM

Cc:

Bonaventure Akinlosotu

Show Details

History: This message has been forwarded.

Richard:

I believe that we have at least two separate unresolved issues regarding fipronil products that hopefully can be quickly and easily resolved.

Firstly there is the question of a renegotiated PRIA date for the four LoradoChem end-use products. As you know the original PRIA date has passed and BA called to ask that I submit before COB on September 29, 2010 a request for a renegotiated PRIA date. This was done in the form of an e-mail requesting that the renegotiated PRIA date acceptable to my client is November 7th 2010. I believe that you called on September 30th but we did not get to speak. Since then I have called twice (believe I left a message on September 30) but then remembered that previously you indicated that it was better to try and contact you via e-mail. LoradoChem as the follow-up to the September 14th (abbreviated CRP meeting), has completed the changes and the addition as requested by Roz Gross and delivered the package by courier last Friday afternoon. Since there is a delay while the submission is processed by the Front End, last evening (October 3, 2010) I sent you by e-mail, a copy of the submission cover letter. Also as previously stated LoradoChem have also removed the 6-pack and the single-pack from the products to be included in the initial approval. This cover letter also indicates that a requested, renegotiated PRIA approval date acceptable to LoradoChem could be as late as November 30, 2010.

The second issue is regarding my September 26th e-mail following the brief September 23 discussion between, Heather Bjornson, BA, you and I about the Fipronext request to have the PRIA category changed from R330 to R310 on correction of shortcomings or amendments to the label use directions, the matrices and the certification with respect to data citation. I would be obliged to receive a written response to this e-mail since it also asked about ensuring a R310 classification for a soon to be submitted application.

As you can surmise I am under pressure from both clients to obtain a response to their respective issues.

Best regards,

Iain

Response to telephone call re requesting a renegotiated PRIA date for the four LoradoChem fipronil containing spot-on products.

Iain Weatherston

to:

Richard Gebken

09/29/2010 01:01 PM

Cc:

Bonaventure Akinlosotu

Show Details

History: This message has been forwarded.

Richard:

In response to BA's call this morning regarding the filing of a request for a renegotiated PRIA date for the four LoradoChem fipronil containing spot-ons. My client wishes to stay with the PRIA date of November 17, 2010 which you offered in a telephone conversation with me on September 2, 2010. In the subsequent meeting with LoradoChem on September 14, Roz said that she had PRIA work out to April 2011, and you said the November 17 date was no longer possible since at the time you made it you were unaware of the CRP issues. Previously Roz had told Dr. Petrick that she had on occasion been told to make exceptions and had expedited CRP reviews. Again I point out that the child safety aspects of the packaging are not in question and the issue with senior testing is resolved by the inclusion of a photograph of in each of the senior testing reports.

At the meeting it was indicated that all of the corrected senior testing reports should be resubmitted in their entirety, the reason given was so that they could be given new MRID numbers. LoradoChem to show good faith is having these reports reworked and will have them into the Agency at the very latest on October 5 (October 1 is the target date for their receipt at the Agency) even although I believe this is entirely unnecessary and the response to the shortcomings could have been handled by a rebuttal letter containing the rationale and the photographs, such a rebuttal document would obtain an MRID number. This is the way an analogous situation was handled recently when the Agency rejected a study for another client.

Also, LoradoChem is willing to limit the original approvals to the 3-card presentation. They are willing to accept this limitation in the approvals in an effort to simplify the CR issues raised by EPA.

LoradoChem will accept a renegotiated PRIA date of November 17, 2010, anything later than this will cause them to seek redress at a higher level within the Agency.

Regards,
Iain

*Added into
OPPIN on 10/5/10* *MFH*

Recommendation of Division Directors Negotiated Due Dates		
Decision #: 429282, 429489, 429492 & 429493	Registration #: 86230 R, E, G, U	Petition #: N/A
Fee Category: R310	PRIA Decision Time Frame: 6 months	
Submitted by: Bonaventure Akinlosotu	Branch: IB	Date: 9/28/2010
Company: LoradoChem, Inc.		
Original Due Date: 9/28/2010 & 9/29/2010	Proposed New Due Date: November 17, 2010	
Previous Negotiated Due Dates: None		
Is the "Fix" in-house? No	If not, date "Fix" expected: 10/12/2010	
<p>Issue (describe in detail):</p> <p>The Agency has 2 current issues that prohibit completion of these registration actions</p> <ul style="list-style-type: none"> • The technical source supply will not be registered until at least November 17, 2010 at the earliest. • The Child Resistant Packaging data furnished with the initial package is deficient, and needs additional supplemental information to correct the deficiencies. 		
<p>Summary of Deficiency Type(s): Not Submitted (N) Deficiencies (D)</p> <p>Product Chemistry: X Acute Tox: X Efficacy: ___ Labeling: <u>X</u> Other (describe): <u>CRP</u></p>		
<p>Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): The Agency contacted the registrant's consultant and informed them of the aforementioned deficiencies. The registrant's consultant discussed various options with the PM, and reviewer and agreed to a new PRIA date. The consultant was also notified that if the source supply for these new registrations has not been registered by November 17, 2010, this date may be extended at the Agencies request. The company has requested and was denied any conditional registrations for the identified deficiencies.</p>		
<p>"75 Day" Letter sent? <u> X </u> (Date sent) 9/28/2010 Yes <u> </u> No and reason for none?</p> <p>At this time the corrections are minor with regards to the product chemistry.</p>		
<p>Rationale for Proposed Due Date: The consultant indicated that the supplemental CRP data will be furnished to the Agency no later than October 5, 2010 (per the consultant's email).</p>		
<p>Registrant notified that this is the last negotiation? <u> </u> Yes <u> X </u> Not Applicable</p>		
Approve: <u> ✓ </u>	Disapprove: <u> </u>	
<p>If disapproved, action to be taken:</p>		
<p>OD or DOD Signature: <u>WTD Landis</u></p>		<p>Date: <u>9-29-10</u></p>



LORADOCHEM CRP data discussion.

Tue 09/14/2010 1:00 PM - 2:00 PM

Attendance is **required** for Bonaventure Akinlosotu

Chair: **Richard Gebken/DC/USEPA/US**

Rooms: RD Small Conference Room E (S-7731)/Potomac Yard One@EPA



This entry has an alarm. The alarm will go off 30 minutes before the entry starts.

Required:

Bonaventure Akinlosotu/DC/USEPA/US@EPA, Deborah McCall/DC/USEPA/US@EPA, IWeatherston@TSGUSA.COM, Marion Johnson/DC/USEPA/US@EPA, Rosalind Gross/DC/USEPA/US@EPA

Description

Agenda below:



LoradoChem 091410 meeting agenda [CRP].docx

I've scheduled this meeting at the request of Ian Weatherston to redress the CRP data issues.

Ian,

Can you please provide a brief agenda by the end of this week, so it can be distributed to others that may be attending the meeting?

Thanks

Richard Gebken

Richard:

Again thank you for the discussion and advice this morning. I contacted the client and discussed both the "renegotiated" PRIA date for the LoradoChem products and the offer to meet them on Tuesday September 14 to discuss the CRP data and how this can be upgraded to be "acceptable."

Regarding the renegotiated PRIA date of November 17, 2010, this is acceptable to my client; do you need me to put in writing the acceptance of this new PRIA date – this has been the procedure followed previously?

LoradoChem accepts the meeting on September 14 and requests that it begin at 1 pm (or later in the afternoon) this is to accommodate Lori Dixon the study director from Great Lakes Marketing who has a previously arranged focus group meeting in California on September 13 but will take a "red eye" and be in DC mid-morning on September 14.

The attendees from LoradoChem will most likely be Dr. John Preston,(Chairman of the Board, Velcera Inc.); Alex Kaufmann, (President of FidoPharm); Dr. David Petrick, (VP Regulatory

Affairs, Velcera Inc.); Dr. Lori Dixon of Great Lakes Manufacturing and myself.

If you can confirm the start time for 1 pm or later on the 14, I would also be obliged to know who will represent the Agency at the meeting.

As we discussed this morning the meeting should not only be restricted to CRP issues but will give both the Agency and LoradoChem to discuss other aspects of the submissions.

Regards,

Iain

Iain Weatherston, Ph.D.

Senior Managing Consultant

Technology Sciences Group Inc.

4061 North 156th Drive

Goodyear, AZ 85395

623-535-4060

iweatherston@tsgusa.com

*Supachai, papae@marrvett.com
623.217.9013 (cell)*

Head Office

1150 18th Street, N.W., Suite 1000

Washington, D.C. 20036

202-223-4392 (receptionist)

www.tsgusa.com

Personal Notes

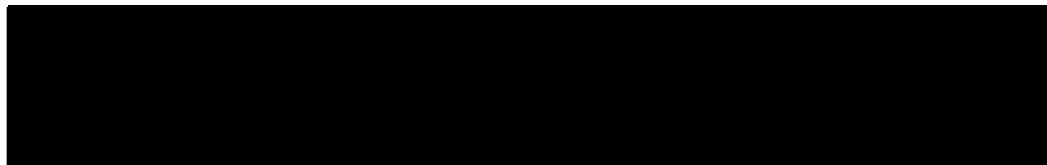
Re: Proposed Alternate Brand Names for the LoradoChem Products

Kimberly Nesci to: Bonaventure Akinlosotu

12/10/2010 03:54 PM

Cc: Clayton Myers, Marion Johnson, Mark Suarez, Richard Gebken

Hi all:



PetArmor?

Bonaventure Akinlosotu

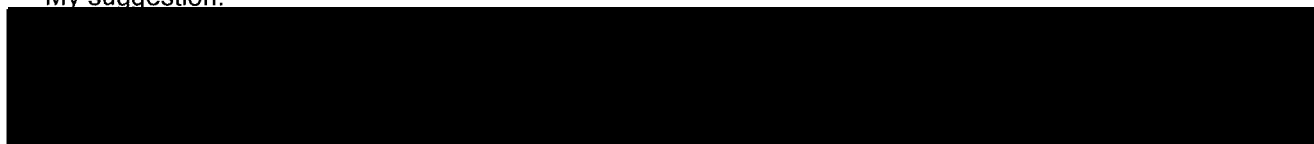
My suggestion:



12/10/2010 03:49:58 PM

From: Bonaventure Akinlosotu/DC/USEPA/US
To: Marion Johnson/DC/USEPA/US@EPA, Richard Gebken/DC/USEPA/US@EPA
Cc: Kimberly Nesci/DC/USEPA/US@EPA, Clayton Myers/DC/USEPA/US@EPA, Mark Suarez/DC/USEPA/US@EPA
Date: 12/10/2010 03:49 PM
Subject: Re: Proposed Alternate Brand Names for the LoradoChem Products

My suggestion:



Your thoughts?

Thx, B.A

-----David Petrick <davidpetrick@comcast.net> wrote: -----

To: Bonaventure Akinlosotu/DC/USEPA/US@EPA, Marion Johnson/DC/USEPA/US@EPA, Richard Gebken/DC/USEPA/US@EPA
From: David Petrick <davidpetrick@comcast.net>
Date: 12/10/2010 01:50PM
Cc: Alex Kaufman <akaufman@velcera.com>, Dennis Steadman <dsteadman@velcera.com>, Iain Weatherston <IWeatherston@TSGUSA.COM>
Subject: Proposed Alternate Brand Names for the LoradoChem Products

Dear Marion, Richard and Bonaventure,

Thank you very much for a productive and EXTREMELY helpful meeting yesterday. We appreciate the clarity of the comments and the assurance of the direction provided. As indicated yesterday, I will be sending along the re-typed Master Label Monday.

As a start, however, as we also discussed yesterday, here are three more trademarks we would propose to use for the products (mono and Combo)

— PetArmor	PetArmor Plus
— TrustGard	TrustGard Plus
— Velcera Fipronil	Velcera Fipronil Plus (S-Methoprene)

Internal deliberative information

We would appreciate feedback as soon as possible from you so that Alex can get the label "plates" made up with suitable TMs so you will have those when you need them as well.

Again, many thanks and I will be in touch Monday by sending along the new Master Labeling Text.

Best Regards,

Dave

Technology Sciences Group Inc.
Western Division
4061 North 156th Drive
Goodyear, AZ 85338
Phone: (623) 535-4060
E-Mail: iweatherston@tsgusa.com

Iain Weatherston, Ph.D.
Senior Managing Consultant



MEMORANDUM

To: Richard Gebken
From: Iain Weatherston
Subject: **Agenda for the September 14, 2010 meeting to discuss CRP and other issues concerning the LoradoChem Inc., applications to register four pet end-use products containing fipronil.**

Meeting is scheduled for Tuesday September 14, 2010 from 2 – 3 pm (eastern time) at the EPA offices at One Potomac Yard, Arlington.

Representing LoradoChem will be:

John Preston, Chairman of the Board, Velcera Inc.
Alex Kaufmann, President of FidoPharm Inc.
David Petrick, VP Regulatory Affairs, Velcera Inc.,
Lori Dixon, Principal, Great Lakes Marketing
Iain Weatherston, Technology Sciences Group Inc.

AGENDA

- | | | | |
|----|--|------------|--------------|
| 1. | Introductions | | [5 minutes] |
| 2. | CRP Testing and Senior Panel Issues | | |
| | (a) Background to testing | D. Petrick | [5 minutes] |
| | (b) Test execution | D. Petrick | [5 minutes] |
| | (c) Scientific difference of opinion | L. Dixon | [10 minutes] |
| | (d) Summary results | D. Petrick | [5 minutes] |
| | (e) Discussion | All | [10 minutes] |
| 3. | Discussion re new negotiated PRIA date of November 17, 2010. | | [5 minutes] |
| 4. | Questions on Product labeling | A. Kaufman | [10 minutes] |
| 5. | Summary and action items | All | [5 minutes] |

MTg w/ Lorado Chem on CRP data Submission.
for 86230-R, E, G, U

Tue, Sept 14, 2010 @ 1-2pm / Rm S-7731

Names	Applications	Phone
B. A. Ambrosio	OPP/RD/IB	703.605.0653
Richard J. Gebb	OPP/RD/IB	703.305-6701
Rosalind LGross	OPP/RD/TRB	703-308-7368
D.M. Petrick	Velera	908-251-3432
Alex Kaufman	Velera	267-757-3609
JOHN PRESTON	Velera	(44) 207 226 2109
IAIN WEATHERSTON	TSG	623-535-4060
LORI DIXON		419-351-3625



TECHNOLOGY
SCIENCES
GROUP
INC.

June 15, 2010

[illegible]

Technology Sciences Group Inc.
Arizona: Regulatory Division
4061 North 156th Drive
Goodyear, AZ 85338
Phone: (623) 535-4060
(623) 217 9013
E-Mail: iweatherston@tsgusa.com



Iain Weatherston, Ph.D.
Senior Managing Consultant
Western Division

Richard Gebken
Product Manager, Team 10
USEPA - OPP - RD - IB
One Potomac Yard
2227 South Crystal Drive
ARLINGTON, VA 22202

June 10, 2010

SUBJECT: Status of applications 86230-R, 86230-E, 86230-G and 86230-U.

COMPANY: LoradoChem Inc., Circa Centre, 12th Floor, 2929 Arch Street, Philadelphia, PA, 18104-2891.

CONTACT: Iain Weatherston, Technology Sciences Group Inc.,
[contact information as per letterhead]

Dear Mr. Gebken:

My clients are concerned and also somewhat confused by pronouncements on the current safety issues surrounding dog and cat spot-on products and how that might impact the registrations of the four subject product under review.

Amongst their concerns are, that the approvals might be delayed because of regulation changes such as:

- 1] Different colors for the applicators of dog products and cat products even although the formulations may be the same since this could involve additional expensive CRP testing.
- 2] Product name differentiation between dog products and cat products.
- 3] The possibility that new protocols will result in the need to undertake further Companion Animal Safety testing or in the case of LoradoChem (and others) who used the cite-all method of data support, undertaking the studies, and this could have an impact on data compensation negotiations.
- 4] Any new mandated labeling, additional warnings, etc that might allow, in this case, the pioneer product to sell under a more favorable label for several months.

Further confusion was caused by the conditions of registration of a new product for Sergeant's [2517-133], where the letter of issuance states "This registration is time-limited and expires two years from the date this product is first released for shipment." There is no statement in the letter that indicates when or if the Agency would convert this registration to an "unconditional" one. One of the conditions of registration is the quarterly filing of enhanced incident reports and sales information. Another restriction is that "only one confidential statement of formula will be filed for this product; no alternate formulations or minor formulation amendments may be submitted or approved for this product."

I have attempted to assuage their concerns that all companies and products are not, or will not be, treated the same. LoradoChem understands and accepts that their products will be conditionally registered with conditions of enhanced adverse incident and sales reporting but are still concerned about the four areas detailed above.

So that we might understand the Agency's current position with the pet spot-on products I would be obliged if comment in a general way on the conditions in the Sergeant's letter of issuance. I am particularly interested in the no alternate formulations or minor formulation restrictions. Is this the way the Agency is going to police the inerts used in these products, and would an amended formulation be acceptable if the inert were cleared by Kit Farwell's committee first?

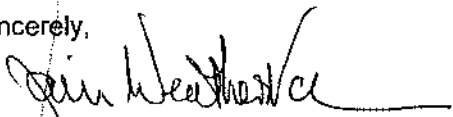
In discussions with LoradoChem Ms. Gross had said that there was a possibility to "self certify" certain future CRP data which will be submitted to the EPA.. I am requesting some clarification on two points.

- a] I never encountered self certification for CRP and believe that what Roz is requesting is that once we have done an internal company review of the test data we submit it to the Agency along with the example statement given at 40 CFR 157.34 (b)(2).
- b] What kinds of future CRP data may be self certified (eg. Change in number of pipettes in a package, pipette size difference, volume differences in the same size pipette, color changes, etc., noting that the pipettes are not the CRP but are in the CRP bubble-pack.

On behalf of LoradoChem I would also ask for a status report on the four applications and if there is any further information that they can provide, that would assist you in the review process.

I thank you for your assistance with these items, and if you require further information or have any questions please contact me at 623-535-4060 or by e-mail at iweatherston@tsgusa.com

Sincerely,



Iain Weatherston
Agent for LoradoChem Inc.

cc: Bonaventure Akinlosotu

Fee for Service

W
{868844L~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: _____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 10

Receipt No.

S- 868844

EPA File Symbol/Reg. No.

86230-E

Pin-Punch Date:

3/5/2010

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R300

Granted: R310

Amount Due: \$ 4571

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: L. J.

Date: 3/9/00

Remarks:

Pending new source of si

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 3-5-10

Experts In-Processing Signature: MF HARRINGTON Date 3-10-10 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: 86230-E | EPA Receipt Date: 3-5-10

Items for Review			Yes	No	N/A*	
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form) a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A) <u>Inerts cleared for non-food use</u>			X		
		yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack) Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)			yes	no	
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use) b) Cite-All (Fee category experts use) c) Applicant owns all data (Fee category experts use)			X		
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

Passed

FG

MRID 480130

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/oppr001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/opppbpd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/oppr001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated



COMPARE TO
FRONTLINE[®]
PLUS
same active
ingredient

FOR CATS
PETARMOR[™] Plus

**KILLS FLEAS, FLEA EGGS, TICKS,
CHEWING LICE & MOSQUITOES**

- Fast action • Kills ticks, including ticks that may transmit Lyme Disease
- Waterproof • Lasting control

Cats & Kittens
only for
8 weeks or older

ACTIVE INGREDIENTS

tipronil (S)-methoprene	9.8%
INERT INGREDIENTS	78.4%
TOTAL	100.0%

KEEP OUT OF REACH
OF CHILDREN
CAUTION

This product is not for use on or distribution to

Lot Number:

PIPETT

3 PIPETTES

3 PIPETTES

Cats & Kittens
only for
8 weeks or older

PETARMOR[™] Plus
FOR CATS

PETARMOR[™] Plus FOR CATS

PETARMOR[™] Plus For Cats acts fast and is an effective, lasting, waterproof, and easy-to-use application for control of fleas, flea eggs, ticks (including all stages of American Dog ticks, Brown Dog ticks, Deer ticks and Lone Star ticks), chewing lice, and mosquitoes ONLY on cats and kittens 8 weeks or older.

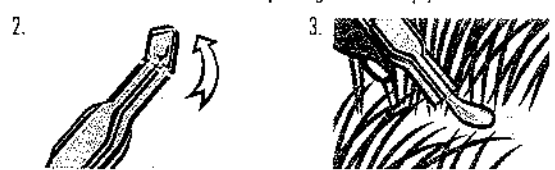
Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply this product. **READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON CATS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.**

For topical application only. Apply PETARMOR[™] Plus For Cats ONLY to cats and kittens aged 8 weeks or older, including or breeding, pregnant, and lactating queens, as indicated below for control of fleas, flea eggs, ticks, chewing lice, and mosquitoes.

How to Apply

1. Open the child resistant package according to the directions on the back of the sealed inner package for each pipette.



2. Snap the tip of the pipette away from you as shown.
3. Part the cat's hair and place the tip of the pipette behind the neck and between the shoulders. Ensure that the entire application of PETARMOR[™] Plus For Cats is contained in a single spot on the cat's skin. Be sure to squeeze the pipette thoroughly so that the entire contents are applied.

Do not apply the product superficially to the cat's hair. Use only one pipette during each application.

Do not touch the area where the application was made until it is dry.

Frequency of Application

Fleas: According to research studies, adult fleas, flea eggs and flea larvae are killed, and all flea stages' development prevented, for up to six weeks following application of tipronil plus (S)-methoprene. If, however, your cat or kitten is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply once every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply PETARMOR[™] Plus For Cats for thirty (30) days.

Please note that there is no need to reapply to lowering your cat's exposure to bathing or water immersion, as PETARMOR[™] Plus For Cats remains effective in those conditions.

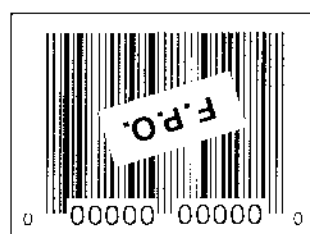
Available Exclusively from: **dePharm, Inc.**
777 Townsend Drive, Suite 170
Farmingdale, NY 11735-5528, USA

EPA Reg. No. 34230-3-85495
EPA Est. No. 8748B-IMP-01

©2011 dePharm, Inc.
All rights reserved.

Questions? Comments?
1-855-908-5166

Made in India



PETARMOR[™] Plus FOR CATS
only for
Cats & Kittens
8 weeks or older
3 PIPETTES

ticks that may transmit Lyme Disease
• Waterproof • Lasting control

only for
Cats & Kittens
8 weeks or older

ACTIVE INGREDIENTS
Fipronil 9.8%
(S)-methoprene 11.8%
INERT INGREDIENTS 78.4%
TOTAL 100.0%

KEEP OUT OF REACH
OF CHILDREN
CAUTION

Contains 3 0.017 fl. oz.
(0.50 ml) pipettes

* This product is
not manufactured
or distributed
by Meriel,
the makers of
Frontline® Plus

**COMPARE TO
FRONTLINE®
PLUS**
same active
ingredients*

PIPETTES 3

For Cat use only

206-5001

3
PIPETTES

***VENDOR/SUPPLIER IS RESPONSIBLE FOR VERIFYING ALL TECHNICAL INFORMATION,
DRUG FACTS, UPC CODES, ITEM CODES AND FINAL DIE LINES.**

<p>CBX</p> <p>Job No. FID-231.04</p> <p>Version 96</p> <p>Contact: Christina A. Kristina B.</p> <p>Artist: Illustrator GSI</p>	<p>PetArmor Plus For Cats Carton</p> <p>File: PetArmorPlus-Cat-Cat-Chai</p> <p>Job No. FID-231.04</p> <p>Version 96</p> <p>Contact: Christina A. Kristina B.</p> <p>Artist: Illustrator GSI</p> <p>Date: 14V JAN 11</p> <p>Artist: Kelli Garrett</p> <p>Designer: Steph Simpson</p> <p>Process: Offset</p> <p>Quoted:</p>	<p>PROCESS COLORS</p> <p>C M Y K</p> <p>LINE COLORS / SPECIAL FINISHING</p> <p>Penline 234 Penline 243</p> <p>PROCESS MATCH</p> <p>Penline 234</p>	<p>MECHANICAL DEVELOPMENT LOG</p> <p>DATE DESCRIPTION</p> <p>05AUG10 Developed from approved design</p> <p>08AUG10 Updated copy as per client revisions 05AUG10</p> <p>09SEP10 Added directions imagery & placed it. Pay off</p> <p>09NOV10 Updated copy as per client revisions 09NOV10</p> <p>10NOV10 Print last release</p> <p>01DEC10 Checked in PetArmor Plus cartons 01DEC10</p> <p>11JAN11 Checked in PetArmor Plus cartons 11JAN11</p> <p>13JAN11 Copy changes per client document from 01DEC10</p>
--	---	--	---



Remove the adhesive backing and attach to your refrigerator

131

***VENDOR/SUPPLIER IS RESPONSIBLE FOR VERIFYING ALL TECHNICAL INFORMATION, DRUG FACTS, UPC CODES, ITEM CODES AND FINAL DIE LINES.**

CBX	PetArmor Plus For Cats Compliance Card	PROCESS COLORS	MECHANICAL DEVELOPMENT LOG	CBX APPROVALS																																
Job: PetArmor Plus For Cats Job No: PFD-301.04 Version: R5 Contact: Christina A., Kristina B. App(s): Illustrator CS3	File: PetArmor-Plus-3cat-Slicker.stl Job No: PFD-301.04 Artist: Keli Garnett Design Dir: Steph Simpson Process: Flexo Output: K	LINE COLORS / SPECIAL FINISHING Pantone 3279	<table><thead><tr><th>DATE</th><th>DESCRIPTION</th><th>REV</th><th>APPROVED BY</th></tr></thead><tbody><tr><td>03SEP10</td><td>Developed from approved design</td><td>R1</td><td></td></tr><tr><td>14SEP10</td><td>Added callouts</td><td>R1</td><td></td></tr><tr><td>09NOV10</td><td>Updated copy as per client revisions 03Nov10</td><td>R2</td><td></td></tr><tr><td>17NOV10</td><td>Print test release</td><td>R2</td><td></td></tr><tr><td>23DEC10</td><td>Changed to PetArmor, copy changes per client document from 12/14/10 to 12/21/10</td><td>R3</td><td></td></tr><tr><td>15JAN11</td><td>Copy changes per client document from 01-05</td><td>R4</td><td></td></tr><tr><td>15JAN11</td><td>Copy changes per client document from 01/13</td><td>R5</td><td></td></tr></tbody></table>	DATE	DESCRIPTION	REV	APPROVED BY	03SEP10	Developed from approved design	R1		14SEP10	Added callouts	R1		09NOV10	Updated copy as per client revisions 03Nov10	R2		17NOV10	Print test release	R2		23DEC10	Changed to PetArmor, copy changes per client document from 12/14/10 to 12/21/10	R3		15JAN11	Copy changes per client document from 01-05	R4		15JAN11	Copy changes per client document from 01/13	R5		
DATE	DESCRIPTION	REV	APPROVED BY																																	
03SEP10	Developed from approved design	R1																																		
14SEP10	Added callouts	R1																																		
09NOV10	Updated copy as per client revisions 03Nov10	R2																																		
17NOV10	Print test release	R2																																		
23DEC10	Changed to PetArmor, copy changes per client document from 12/14/10 to 12/21/10	R3																																		
15JAN11	Copy changes per client document from 01-05	R4																																		
15JAN11	Copy changes per client document from 01/13	R5																																		
CLIENT IS RESPONSIBLE FOR PROOFREADING ALL COPY BEFORE EXECUTION OF JOB. THE DESIGN FIRM MAKES EVERY REASONABLE EFFORT TO ENSURE ERROR-FREE SUBMISSION OF COPY, BUT WILL BE LIMITED IN ITS ABILITY TO THE CORRECTION OF ANY ERRORS IN COPY. CLIENT'S LEGAL DEPARTMENT CONFIRMS THAT ALL LEGAL REQUIREMENTS HAVE BEEN MET. COLOR SEPARATIONS, PRE-PRESS SERVICE BUREAUS AND/OR PRINTERS ARE RESPONSIBLE FOR CHECKING FINAL MECHANICAL DRAWINGS FOR TOLERANCES, REGISTRATION, ACCURACY IN MEASUREMENTS, AND CONSTRUCTION DETAILS BEFORE PLATES OR CYLINDERS ARE MADE. COLOR PROOFS AND ANY CHANGES MADE TO ACCOMMODATE PRODUCTION REQUIREMENTS MUST BE SUBMITTED TO CLIENT FOR APPROVAL. PANTONE® is a registered trademark of Pantone, Inc.																																				

PETARMORTM Plus FOR CATS

Only for use on cats and kittens 8 weeks or older

PETARMORTM Plus For Cats is a topical application for fast action and lasting control of fleas, flea eggs, ticks, chewing lice, and mosquitoes.

Active Ingredients

Fipronil	9.8%
(S)-methoprene	11.8%
INERT INGREDIENTS	78.4%
TOTAL	100.0%

Compare to Frontline[®] Plus same active ingredients*

KEEP OUT OF REACH OF CHILDREN

CAUTION

PETARMORTM Plus For Cats acts fast and is an effective, lasting, waterproof, one easy-to-use application for control of fleas, ticks, chewing lice, and mosquitoes on cats and kittens. When used as directed, PETARMORTM Plus For Cats can stop infestations of fleas, ticks, and chewing lice, and help to prevent reinfestation on cats and kittens, including on breeding, pregnant, and lactating queens.

Specifically, PETARMORTM Plus For Cats kills, controls and prevents infestations of:

1. Adult fleas, flea eggs, and flea larvae, including fleas which could cause flea allergy dermatitis, and can prevent the further development of fleas at the egg, larval and pupal stages;
2. Brown Dog tick, the American Dog tick, the Lone Star tick, and the Deer tick (that may transmit Lyme Disease), at all stages; and
3. Chewing lice infestations;

4. Kills mosquitoes.

PETARMORTM Plus For Cats contains the active ingredient fipronil and the insect growth regulator (IGR) (S)-methoprene.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply this

product. READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON CATS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Apply PETARMORTM Plus For Cats ONLY to cats and kittens aged 8 weeks or older, including on breeding, pregnant, and lactating queens, as indicated below for control of fleas, flea eggs, ticks, chewing lice, and mosquitoes:

How to Apply

1. Open the child resistant package according to the directions on the back of the sealed inner package for each pipette.



2. Snap the tip of the pipette away from you as shown.

3. Part the cat's hair and place the tip of the pipette to the skin level behind the neck and between the shoulders. Ensure that the entire application of PETARMORTM Plus For Cats is contained in a single spot on the cat's skin. Be sure to squeeze the pipette thoroughly so that the entire contents are applied.

Do not apply the product superficially to the cat's hair. Use only one pipette during each application.

Do not touch the area where the application was made until it is dry.

Frequency of Application

Fleas: According to research studies, adult fleas, flea eggs, and flea larvae are killed, and all flea stages' development prevented for up to six weeks following an application of fipronil plus (S)-methoprene. If, however, your cat or kitten is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply once every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply PETARMORTM Plus For Cats for thirty (30) days.

Please note that there is no need to reapply following your cat's exposure to bathing or water immersion, as PETARMORTM Plus For Cats remains effective in these conditions.

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

Storage: Store unused application pipettes in the original child-resistant container and outer box only, out of reach of children and animals.

Pesticide Disposal: If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Container Disposal: Nonrefillable container. If empty: Do not reuse this container. Place in trash or offer for recycling if available.

First Aid

Have the product container or label with you when calling a poison control center or doctor, or if going for treatment.

If Swallowed: Immediately call a poison control center or doctor for treatment advice. Have the person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

If on Skin: Rinse skin with plenty of soap and water. Get medical attention if irritation persists.

Precautions

Hazards to Humans: Caution.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Hazards to Domestic Animals:

For external use only. Do not use on kittens under 8 weeks of age. Sensitivities may occur after using ANY pesticide product for pets. While temporary irritation of the application area may occur, if signs of continued sensitivity occur, consult a veterinarian immediately.

*VENDOR/SUPPLIER IS RESPONSIBLE FOR VERIFYING ALL TECHNICAL INFORMATION, DRUG FACTS, UPC CODES, ITEM CODES AND FINAL DIE LINES.

CBX		PetArmor Plus For Cats Insert Card	
On Print Date	14 JAN 11	File	PetArmor Plus Cats Insert Card.dtl
Printed Date	14 JAN 11	Job No	FID-021.04
Printed By	14 JAN 11	Artist	Kelli Garnett
Printed At	14 JAN 11	Version	R5
Printed On	14 JAN 11	Design Dir	Steph Simpson
Printed For	14 JAN 11	Contact	Christine A. Kestner
Printed By	14 JAN 11	Process	Offset
Printed At	14 JAN 11	Applic	Illustrator CS3
Printed On	14 JAN 11	Output	Output

PROCESS COLORS

K

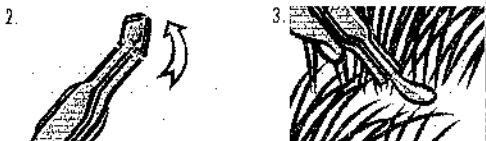
MECHANICAL DEVELOPMENT LOG		CBX APPROVALS				
DATE	DESCRIPTION	APP	DES	ART	PRO	REP
12AUG10	Developed from approved design	R1				
18AUG10	Updated copy as per client revision 05Aug10	R1				
08NOV10	Updated copy as per client revision 04Nov10	R2				
17NOV10	Print test release	R2				
30DEC10	Original PetArmor copy changes per client document 12/14/10, 12/21/10, 12/22/10	R3				
07JAN11	Copy changes per client document 01/05/11	R4				
13JAN11	Copy changes per client document 01/13/11	R5				

product. READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON CATS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Apply PETARMOR™ Plus For Cats **ONLY** to cats and kittens aged 8 weeks or older, including on breeding, pregnant, and lactating queens, as indicated below for control of fleas, flea eggs, ticks, chewing lice, and mosquitoes:

How to Apply

1. Open the child resistant package according to the directions on the back of the sealed inner package for each pipette.



2. Snap the tip of the pipette away from you as shown.
3. Part the cat's hair and place the tip of the pipette to the skin level behind the neck and between the shoulders. Ensure that the entire application of PETARMOR™ Plus For Cats is contained in a single spot on the cat's skin. Be sure to squeeze the pipette thoroughly so that the entire contents are applied. Do not apply the product superficially to the cat's hair. Use only one pipette during each application.

Do not touch the area where the application was made until it is dry.

Frequency of Application

Fleas: According to research studies, adult fleas, flea eggs, and flea larvae are killed, and all flea stages' development prevented for up to six weeks following an application of fipronil plus (S)-methoprene. If, however, your cat or kitten is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply once every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply PETARMOR™ Plus For Cats for thirty (30) days.

Please note that there is no need to reapply following your cat's exposure to bathing or water immersion, as PETARMOR™ Plus For Cats remains effective in those conditions.

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

Storage: Store unused application pipettes in the original child-resistant container and outer box only, out of reach of children and animals.

Pesticide Disposal: If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Container Disposal: Non-refillable container. If empty: Do not reuse this container. Place in trash or offer for recycling if available.

First Aid

Have the product container or label with you when calling a poison control center or doctor, or if going for treatment.

If Swallowed: Immediately call a poison control center or doctor for treatment advice. Have the person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

If on Skin: Rinse skin with plenty of soap and water. Get medical attention if irritation persists.

Precautions

Hazards to Humans: Caution.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Hazards to Domestic Animals:

For external use only. Do not use on kittens under 8 weeks of age. Sensitivities may occur after using ANY pesticide product for pets. While temporary irritation at the application area may occur, if signs of continued sensitivity occur, consult a veterinarian immediately.

Should any unusual reactions to the application occur, do not reapply before consulting with a veterinarian. Certain medications can interact with pesticides. Consult with your veterinarian before using this product on medicated, debilitated, or aged cats. Call 1-888-908-TICK for 24-hour assistance.

Physical or Chemical

Flammable: Keep away from heat and open flame.

Warranty

To the extent consistent with applicable law, Sellers make no warranty, express or implied, concerning the use of this product other than as indicated on the labeling. Buyer assumes all risk of use and handling of the product when such use and handling are contrary to the label instructions.

For Cat use only.

* This product is not manufactured or distributed by Meriel, the makers of Frontline® Plus

Available Exclusively from FidoPharm, Inc.
777 Township Line Road, Suite 170
Yardley, PA 19067-5508 USA

EPA Reg. No. 86236-3-85495
EPA Est. No. 87688-BIG-01

©2011 FidoPharm, Inc.
All rights reserved.

Questions? Comments?
1-888-908-TICK

Made in Japan

2013001

***VENDOR/SUPPLIER IS RESPONSIBLE FOR VERIFYING ALL TECHNICAL INFORMATION, DRUG FACTS, UPC CODES, ITEM CODES AND FINAL DIE LINES.**

CBX

Client: FIDOPHARM
Product: PETARMOR PLUS FOR CATS
Job: FID-001.04
Date: 14 JAN 11



PetArmorPlus For Cats Insert Card

File: PetArmorPlus-Cats-InsertCard Date: 14 JAN 11
Job No: FID-001.04 Artist: Kelli Garrett
Version: R5 Designer: Steph Simpson
Contact: Christine A. Kristina B. Process: Offset
App(s): Illustrator CS3 Output(s):

PROCESS COLORS

K

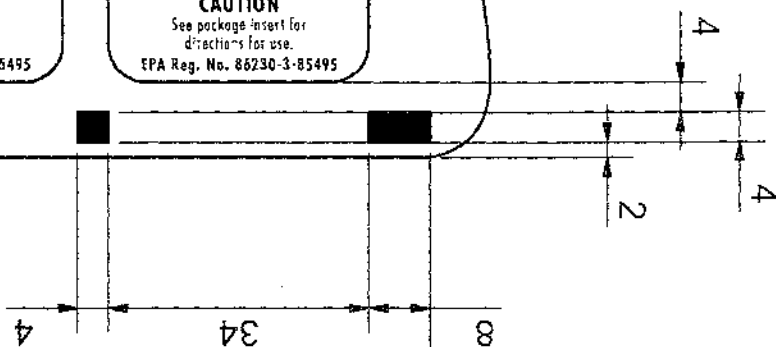
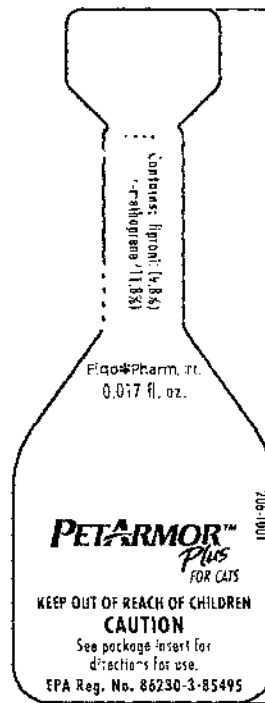
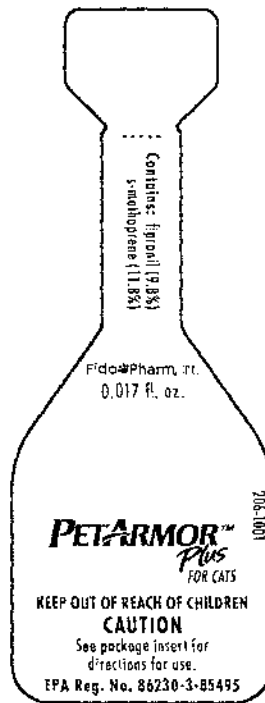
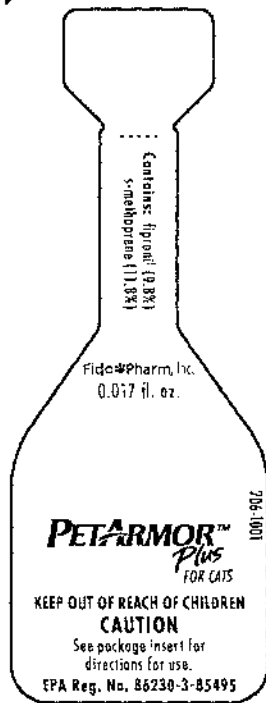
MECHANICAL DEVELOPMENT LOG

DATE	DESCRIPTION	APP	PROG	DES	ART	OP
24AUG10	Developed from approved design	R1				
18AUG10	Updated copy as per client revisions 05AUG10	R1				
09NOV10	Updated copy as per client revisions 04NOV10	R2				
17NOV10	Print test release	R2				
30DEC10	Changed to PETARMOR, copy changes per client payment from 1/21/11, 3/22/11, 12/23/10	R3				
07JAN11	Copy changes per client document from 01/05	R4				

CBX APPROVALS

CLIENT IS RESPONSIBLE FOR PROOFREADING ALL COPY BEFORE EXECUTION OF JOB. THE DESIGN FIRM MAKES EVERY REASONABLE EFFORT TO ENSURE ERROR-FREE SUBMISSION OF COPY BUT WILL BE IN NO WAY LIABLE TO THE CORRECTION OF ANY ERRORS IN COPY. CLIENTS' LEGAL DEPARTMENT CONFIRMS THAT ALL LEGAL REQUIREMENTS HAVE BEEN MET. COLOR SERVICES: PREPRESS SERVICE, BUFFALO AND/OR PRINTERS ARE RESPONSIBLE FOR CHECKING FINAL MECHANICAL DRAWINGS FOR COLOR, FINISHES, REGISTRATION, ACCURACY IN MEASUREMENTS, AND CONSTRUCTION DETAILS BEFORE PLATES OR


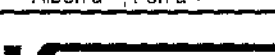
135



$$399.5 + 0.33 = 399.83$$

*VENDOR/SUPPLIER IS RESPONSIBLE FOR VERIFYING ALL TECHNICAL INFORMATION, DRUG FACTS, UPC CODES, ITEM CODES AND FINAL DIE LINES.

CBX		PetArmor Plus For Cats Pipette		PROCESS COLORS		MECHANICAL DEVELOPMENT LOG				CBX APPROVALS			
Buyer: J. J. Smith	File: PetArmor Plus-Gats-Pipette.s	Date: 14 JAN 10	Artist: Adam Doran	Process: Offset	Output:	DATE	DESCRIPTION	VER.	REQ.	DES.	APP.	DATE	
Buyer: J. J. Smith	Job No: FID-001.04	Artist: Adam Doran	Design Dir: Steph Simpson	Process: Offset	Output:	18 AUG '09	Developed from approved design	R1					
Buyer: J. J. Smith	Version: R4	Design Dir: Steph Simpson	Process: Offset	Output:	Output:	17 NOV '09	Updated EPA reg. number. Print last release	R1					
Buyer: J. J. Smith	Contact: Christine Arakelian	Design Dir: Steph Simpson	Process: Offset	Output:	Output:	03 DEC '09	EPA Feedback, Reader	R2					
Buyer: J. J. Smith	App(s): Illustrator CS3	Design Dir: Steph Simpson	Process: Offset	Output:	Output:	07 JAN '10	Copy changes per client document from 01-10	R3					
CLIENT IS RESPONSIBLE FOR PROOFREADING ALL COPY BEFORE EXECUTION OF JOB. THE DESIGN FIRM MAKES EVERY REASONABLE EFFORT TO ENSURE ERROR-FREE SUBMISSION OF COPY, BUT WILL BE LIMITED IN LIABILITY TO THE CORRECTION OF ANY ERRORS IN COPY. CLIENT'S LEGAL DEPARTMENT CERTAINS THAT ALL LEGAL REQUIREMENTS HAVE BEEN MET.						13 JAN '11	Copy changes per client document from 01-10	R4					
COLOR SEPARATIONS, PRE-PRESS SERVICE BUREAUS AND/OR PRINTERS ARE RESPONSIBLE FOR CHECKING FINAL MECHANICAL DRAWINGS FOR TOLERANCES, REGISTRATION, ACCURACY IN MEASUREMENTS AND CONSTRUCTION DETAILS BEFORE PLATES OR CYLINDERS ARE MADE. COLOR PROOFS AND ANY CHANGES MADE TO ADJUST COLOR PRODUCTION REQUIREMENTS MUST BE SUBMITTED TO CLIENT FOR APPROVAL. PRINTWORK is a registered trademark of Ralston, Inc.													

Raccordi d' utensile non quotati R.0.8 max		Smussi non quotati Sm=0.5x45-		Togliere spigoli vivi e cave di taglio			
TRATT. SUPERFICIALE		TRATT. TERMICO		P. Kg	FOGLIO N. 1	DISEGN. NERI	DATA 28/05/2010
SCOSTAMENTI QUOTE LIBERE IT 10 Alberi a - , Fori a +		TOLL. GENER. DI FORMA ⊥ // 0.10 ⊙ 0.05		SOSTITUISCE IL		SCALA 1:1	
		PROGETTO VT240-3		GRUPPO - MACCHINA		Q.TA' PEZZI	
		DESCRIZIONE		DIS. N.		FORM.	

Valmatic

Printing Area

Inkjet Printing Area

Foil width 239 mm

113 mm

93 mm

206-2001

Pfizer
PETARMOR[™] Plus
FOR CATS

TO OPEN PACKAGE:
Cut across the top as shown.
Peel down the foil completely
before refilling blister.

Cut—0.017 ft. oz.
Lot No:

93 mm

206-2001

Pfizer
PETARMOR[™] Plus
FOR CATS

TO OPEN PACKAGE:
Cut across the top as shown.
Peel down the foil completely
before refilling blister.

Cut—0.017 ft. oz.
Lot No:

93 mm

206-2001

Pfizer
PETARMOR[™] Plus
FOR CATS

TO OPEN PACKAGE:
Cut across the top as shown.
Peel down the foil completely
before refilling blister.

Cut—0.017 ft. oz.
Lot No:

93 mm

206-2001

PETARMOR[™] Plus
FOR CATS

TO OPEN PACKAGE:
Cut across the top as shown.
Peel down the foil completely
before refilling blister.

Cut—0.017 ft. oz.
Lot No:

93 mm

206-2001

PETARMOR[™] Plus
FOR CATS

TO OPEN PACKAGE:
Cut across the top as shown.
Peel down the foil completely
before refilling blister.

Cut—0.017 ft. oz.
Lot No:

93 mm

206-2001

PETARMOR[™] Plus
FOR CATS

TO OPEN PACKAGE:
Cut across the top as shown.
Peel down the foil completely
before refilling blister.

Cut—0.017 ft. oz.
Lot No:

Inkjet Printing Area

***VENDOR/SUPPLIER IS RESPONSIBLE FOR VERIFYING ALL TECHNICAL INFORMATION, DRUG FACTS, UPC CODES, ITEM CODES AND FINAL DIE LINES.**

CBX

Customer Name
Customer Address
Customer City/State/Zip
Customer Phone/Fax
Customer E-mail



PetArmor Plus For Cats Blister

File PetArmorPlus-Cats-Blisteral Date 14 JAN 11
Job No. FID-001,03 Artist Kelli Garnett
Version R4 Design Dir: Steph Simpson
Contact: Christine Arakelian Process: Flore
Appr'd: Illustrator CS3 Output:

PROCESS COLORS

K

MECHANICAL DEVELOPMENT LOG

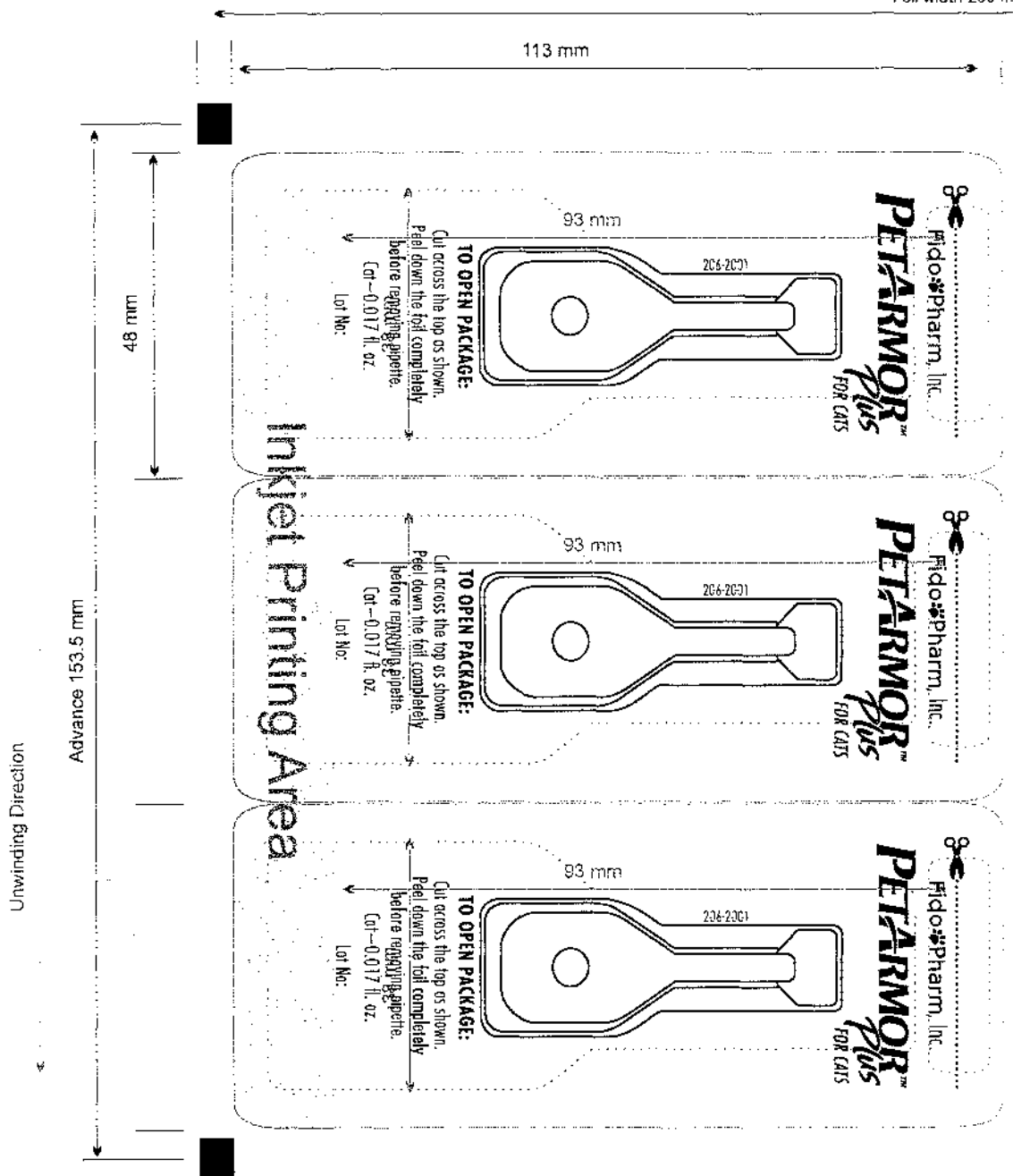
DATE	DESCRIPTION	REV	BY	CHK
19Mar10	Developed from approved design	R1		
05Aug10	Revised Pfizer logo supplied by client	R1		
17Aug10	Changes as per client document 05AUG10	R1		
07SEP10	Enlarged scissors as per client document 07SEP10	R1		
17NOV10	Print test release	R1		
30DEC10	Changed to PetArmor, copy changes per client document from 10/15/10, 10/27/10	R2		
07JAN11	Copy changes per client document from 01/05/11	R3		
13JAN11	Copy changes per client document from 01/13/11	R		

CBX APPROVALS

CLIENT IS RESPONSIBLE FOR PROVIDING ALL COPY TO BE EXECUTED. THE DESIGN FIRM MAKES EVERY REASONABLE EFFORT TO ENSURE ERROR-FREE SUBMISSION OF COPY BUT WILL BE LIMITED IN LIABILITY TO THE CORRECTION OF ANY ERRORS IN COPY. CLIENT'S LEGAL DEPARTMENT CONFIRMS THAT ALL LEGAL REQUIREMENTS HAVE BEEN MET.
COLOR SUPPLIERS, PRE-PRESS SERVICE BUREAUS AND/OR PRINTERS ARE RESPONSIBLE FOR CHECKING FINAL MECHANICAL DRAWINGS FOR TOLERANCES, REGISTRATION, ACCURACY IN MEASUREMENTS, AND CONSTRUCTION DETAILS FOR PLATES OR CYLINDERS ARE MADE. COLOR PROOFS AND ANY CHANGES MADE TO ACCOMMODATE PRODUCTION REQUIREMENTS MUST BE SUBMITTED TO CLIENT FOR APPROVAL. PETARMOR is a registered trademark of Pfizer Inc.

Printing Area

Foil width 239 m



***VENDOR/SUPPLIER IS RESPONSIBLE FOR VERIFYING ALL TECHNICAL INFORMATION, DRUG FACTS, UPC CODES, ITEM CODES AND FINAL DIE LINES.**

CBX Project: PetArmor Plus For Cats Job No: FD-001.03 Version: RA Contact: Christine Arakelian App(s): Illustrator CS3	PetArmor Plus For Cats Blister File: PetArmorPlus-Cats-Blistera Date: 14 JAN 11 Artist: Kelli Garnett Design Dir: Steph Simpson Process: Flexo Output:	PROCESS CCLD K
CLIENT IS RESPONSIBLE FOR PROOFREADING ALL COPY BEFORE SUBMISSION OF JOB. THE DESIGN FIRM MAKES EVERY REASONABLE EFFORT TO ENSURE ERROR FREE SUBMISSION OF COPY, BUT WILL BE LIMITED IN LIABILITY TO THE CORRECTION OF ANY ERRORS IN COPY. CLIENT'S LEGAL DEPARTMENT CONFIRMS THAT ALL LEGAL REQUIREMENTS HAVE BEEN MET. COLOR SEPARATIONS, PRE-PRESS SERVICE BUREAUS AND/OR PRINTERS ARE RESPONSIBLE FOR CHECKING FINAL MECHANICAL DRAWINGS FOR COLOR ERRORS, REGISTRATION, ACCURACY IN MEASUREMENTS, AND CONSTRUCTION DETAILS BEFORE PLATES OR CYLINDERS ARE MADE. COLOR PROOFS AND ANY CHANGES MADE TO ACCOMMODATE PRODUCTION REQUIREMENTS MUST BE SUBMITTED TO THE FIRM FOR APPROVAL. PetArmor Plus is a registered trademark of Parvex, Inc.		



Technology Sciences Group Inc.

4061 N. 156th Drive
Goodyear, AZ 85395
Direct: (623)-535-4060
Cell: 217-9013
E-Mail: iweatherston@tsgusa.com

Iain Weatherston Ph.D.
Senior Managing Consultant

Document Processing Desk [FPL]
U.S. EPA – OPP – RD – IB
Attention: Richard Gebken
One Potomac Yard
2777 South Crystal Drive,
ARLINGTON, VA 22202

January 19, 2010

SUBJECT: Submission of Final Printed Labeling.

COMPANY: LoradoChem. Inc., Cira Centre, 12th Floor, 2929 Arch Street,
Philadelphia, PA 19104-2871.

CONTACT: Iain Weatherston, Ph.D.
[contact information as per letterhead]

PRODUCTS: LC-2010-1 Fipronil for Cats [86230-1]
LC-2010-2 Fipronil for Dogs [86230-2]
LC-2010-3 Fipronil & S-Methoprene for Cats [86230-3]
LC-2010-4 Fipronil & S-Methoprene for Dogs [86230-4]

Dear Richard:

As required by the letters of issuance of these four end-use product, please find enclosed for each product a fully executed application form [EPA Form 8570-1] and two copies of the product labeling.

LoradoChem Inc., at this time has no intention of marketing these products under their own label, so the labels submitted are for four subregistered products to be marketed by FidoPharm, Inc [85495]. The Agency has received the documentation [8570-5] for each of these products.

If you require further information, or have any questions, please do not hesitate to contact me at iweatherston@tsgusa.com or by phone at 623-535-4060.

Sincerely,

Enclosures: 2 copies of the FPL for each of the four subject products
Executed 8570-1 for each of the four subject products.



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:

X Registration
Reregistration
(under FIFRA, as amended)

EPA Reg. Number:

86230-2

Date of Issuance:

JAN 10 2011

Term of Issuance:

Conditional

Name of Pesticide Product:

LC-2010-2 Fipronil for Dogs

Name and Address of Registrant (include ZIP Code):

LoradoChem, Inc.
Cira Centre, 12th. Floor
29202 Arch Street
Philadelphia, PA 19104-2891

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

(continued on page 2)

Signature of Approving Official:

See Page 3

Richard J. Gebken, Product Manager (10)
Insecticide Branch, Registration Division (7505P)

Date:

JAN 10 2011

EPA Form 8570-6

2. Make the following change to the label:
 - a. Change the product registration number to "EPA Reg. No. 86230-4"
3. Agency requirements with respect to the continued registration:
 - a. The registration for this product is time-limited and expires two years from the date this product is released for shipment bearing the revised language. You must provide the Agency with a projected release for shipment date within 30 days of the date of this letter. The Agency will calculate the expiration date based on the projected release date until an actual release date is provided in writing.
4. Reporting of incident data for this product:
 - a. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on October 1, 2010. The quarterly reports are due two months after each quarter ends.

Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kimberly Nesci).

The following is a list of information that must be included in the quarterly reports for each incident:

- EPA Registration Number
 - Product name (brand name)
 - Lot #
 - Where purchased: internet, store, veterinarian
 - Active Ingredient(s)
 - Weight range for product
 - Date on which incident occurred. (mm/dd/yyyy)
 - State in which the incident occurred. (standard 2 letter abbreviation)
 - Registrant case #
 - Species: dog, cat, other (specify)
 - Breed: (as reported by pet owner)
 - Age: months or years
 - Sex: M, F, or neutered
 - Weight: pounds
 - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
 - Body System: neurological, dermatological, GI, respiratory, ocular, other
 - Major signs noted with separate column for each sign, using standard terminology
 - Time to Onset: (hours, days)
 - Treated by veterinarian: yes or no
 - First time product used: yes or no
 - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
 - Any known precondition
 - EPA Severity Code: death, major, moderate, minor
 - Outcome: died, recovered, still treated, unknown
- b. **Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:**
 - All incidents should be reported including all minor dermal and ocular irritation reports.
 - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular> oral> dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.

- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label (if applicable).
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range (if applicable).
- Table showing number of incidents for each dog breed.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

5. Other Comments:

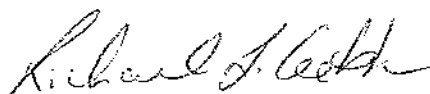
- This product has met the requirements for Child Resistant Packaging (CRP). however, the Agency reserves the right to reevaluate the associated data if:
 - an incident report shows any problems in human, and/or
 - epidemiological evidence indicates a problem once the products reach the marketplace.
- Consider limiting the formulations of each product to one basic confidential statement of formula, if applicable. The Agency may require this in the future. It is possible that no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
- If the Agency determines that future mitigation measures are necessary for all pet spot-on products, you will be informed, and be expected to comply. If mitigation measures are necessary, the Agency may take appropriate regulatory actions.

- You must submit two copies of the revised final printed labels (Master label and Production Copies) for all sizes for the Agency records, before the product is released for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Richard J. Gebken



Product Manager (10)
Insecticide Branch
Registration Division (7505P)

Enclosure: Label stamped "Accepted with Comments"

JEPA REG. NO. 86230-2 / DECISION 429489

Master Label containing:

Sublabel A: Box Label

Sublabel B: Package Insert

Sublabel C: Labeling on the Child Resistant Package

Sublabel D: Labeling on the Pipette

Sublabel E: Stickers for Re-application Reminders

LC-2010-2 FIPRONIL FOR DOGS

ACTIVE INGREDIENT

Fipronil.....9.7%

(Picture of dog)

INERT INGREDIENTS.....90.3%

TOTAL.....100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Contains X-0.0XX fl.oz. (X.xx mL) pipette(s)

EPA Reg. No. 86230-E

ACCEPTED
with COMMENTS
In EPA Letter Dated:
JAN 10 2011
Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
86230-E

Sublabel A: Box Label

[Front Panel of Box]

LC-2010-2
[Alternate Brand Names]
[PetArmor™]
[TrustGard™]
[Velcera® Fipronil]

FIPRONIL FOR DOGS

3 (Drawing of pipette)
Pipettes

Kills fleas, ticks, chewing lice & Mosquitoes

- Fast action
- Kills ticks, including ticks that may transmit Lyme Disease
- Kills mosquitoes
- Waterproof
- Lasting control

[Only use on dogs and puppies up to 22 lbs. 8 weeks or older]

Or

[Only use on dogs 23-44 lbs. 8 weeks or older]

Or

[Only use on dogs 45-88 lbs.]

Or

[Only use on dogs 89-132 lbs.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

ACTIVE INGREDIENT

Fipronil.....9.7%

(Picture of dog)

INERT INGREDIENTS.....90.3%

TOTAL.....100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[Contains 3-0.023 fl.oz (0.067 mL) pipettes]

Or

[Contains 3-0.045 fl.oz. (1.34 mL) pipettes]

Or

[Contains 3-0.091 fl.oz. (2.68 mL) pipettes]

Or
[Contains 3-0.136 fl.oz (4.02 mL) pipettes]
[Label identifiers that will be used to identify each respective package size contained within the box.]

Compare to Frontline® Top Spot same active ingredient*

*This product is not manufactured by Merial, the makers of Frontline®

[Back Panel of Box]

LC-2010-2 [or other approved alternate brand name] Fipronil For Dogs
LC-2010-2 [or other approved alternate brand name] For Dogs acts fast and is an effective, lasting, waterproof, and easy-to-use application for control of fleas, ticks, chewing lice, and mosquitoes [ONLY on dogs and puppies weighing up to 22 lbs. and 8 weeks or older.]
Or ...[ONLY on dogs weighing 23-44 lbs. and 8 weeks or older.]
Or ...[ONLY on dogs weighing 45-88 lbs.]
Or ...[ONLY on dogs weighing 89-132 lbs.]
[Label identifiers that will be used to identify each respective package size contained within the box.]

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply this product. READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Apply LC-2010-2 [or other approved alternate brand name] For Dogs ONLY to dogs and puppies aged 8 weeks or older, including on breeding, pregnant, and lactating bitches, as indicated below for control of fleas, ticks (including all stages of American Dog ticks, Brown Dog ticks, Deer ticks and Lone Star ticks), chewing lice, and mosquitoes:

How to Apply

Drawing of a pipette
Drawing of treating animal

1. Open the child resistant package according to the directions on the back of the sealed inner package for each pipette.
2. Snap the tip of the pipette away from you as shown

3. Part the dog's hair and place the tip of the pipette behind the neck and between the shoulders. Ensure that the entire application of LC-2010-2 [or other approved alternate brand name] For Dogs is contained in a single spot on the dog's skin. Be sure to squeeze the pipette thoroughly so that the entire contents are applied.

Do not apply the product superficially to the dog's hair. Use only one pipette during each application.

Do not touch the area where the application was made until it is dry.

LC-2010-2 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

Frequency of Application

Fleas: According to research studies, adult fleas are killed for up to three months following an application of fipronil. If, however, your dog or puppy is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply once every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply LC-2010-2 [or other approved alternate brand name] For Dogs for thirty (30) days.

LoradoChem, Inc.
Circa Center, 12th Floor
2929 Arch Street
Philadelphia, PA 18104-2891 USA

EPA Reg. No. 86230-E

EPA Est. No. 87688-IND-01

©2010 LoradoChem, Inc. All rights reserved.

(Drawing of telephone receiver) Questions? Comments?
1-888-908-TICK

Made in India

[Top Panel of Box]

LC-2010-2 [or other approved alternate brand name] **FIPRONIL FOR DOGS**

[Only use on dogs and puppies up to 22 lbs. 8 weeks or older] 3 (Drawing of pipette)
Or Pipettes
[Only use on dogs 23-44 lbs. 8 weeks or older]
Or
[Only use on dogs 45-88 lbs.]
Or
[Only use on dogs 89-132 lbs.]
[Label identifiers that will be used to identify each respective package size contained
within the box.]

[Bottom Panel of Box]

For Dog use Only

[Right side panel of Box]

LC-2010-2 [or other approved alternate brand name] **Fipronil For Dogs**

[Only use on dogs and puppies up to 22 lbs. 8 weeks or older] 3 (Drawing of pipette)
Or Pipettes
[Only use on dogs 23-44 lbs. 8 weeks or older]
Or
[Only use on dogs 45-88 lbs.]
Or
[Only use on dogs 89-132 lbs.]
[Label identifiers that will be used to identify each respective package size contained
within the box.]

[Left side panel of Box]

Lot Number: 3 (Drawing of pipette)
pipettes

Sublabel B: Package Insert

LC-2010-2 [or other approved alternate brand name] Fipronil For Dogs

Only for use on dogs and puppies 8 weeks or older

LC-2010-2 [or other approved alternate brand name] FOR DOGS is a topical application for fast action and lasting control of fleas, ticks, chewing lice and mosquitoes.

ACTIVE INGREDIENT

Fipronil.....	9.7%
INERT INGREDIENTS.....	90.3%
TOTAL.....	100.0%

Compare to Frontline® Top Spot same active ingredient*

KEEP OUT OF REACH OF CHILDREN

CAUTION

LC-2010-2 [or other approved alternate brand name] For Dogs acts fast and is an effective, lasting, waterproof, and easy-to-use application for control of fleas, ticks, chewing lice, and mosquitoes on dogs and puppies. When used as directed, LC-2010-2 [or other approved alternate brand name] For Dogs can stop infestations of fleas, ticks, chewing lice, and mosquitoes and help to prevent re-infestation on dogs and puppies, including on breeding, pregnant and lactating bitches. LC-2010-2 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

Specifically, LC-2010-2 [or other approved alternate brand name] For Dogs kills, controls and prevents infestations of:

- 1) Newly emerged adult fleas prior to egg-laying, including fleas which could cause flea allergy dermatitis;
- 2) Brown Dog tick, the American Dog tick, the Lone Star tick, and the Deer tick (including ticks that may transmit Lyme Disease), at all stages;
- 3) Chewing lice infestations;
- 4) Kills mosquitoes.

LC-2010-2 [or other approved alternate brand name] FOR DOGS contains the active ingredient fipronil.

Directions For Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply this product. READ ENTIRE LABEL AND

ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Apply LC-2010-2 [or other approved alternate brand name] For Dogs **ONLY** to dogs and puppies aged 8 weeks or older, including on breeding, pregnant, and lactating bitches, as indicated below for control of fleas, ticks, chewing lice, and mosquitoes:

How to Apply

Drawing of a pipette

Drawing of treating animal

1. Open the child resistant package according to the directions on the back of the sealed inner package for each pipette.
2. Snap the tip of the pipette away from you as shown.
3. Part the dog's hair and place the tip of the pipette behind the neck and between the shoulders. Ensure that the entire application of LC-2010-2 [or other approved alternate brand name] For Dogs is contained in a single spot on the dog's skin. Be sure to squeeze the applicator thoroughly so that the entire contents are applied.

Do not apply the product superficially to the dog's hair. Use only one pipette during each application.

Do not touch the area where the application was made until it is dry.

LC-2010-2 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

Frequency of Application

Fleas: According to research studies, adult fleas are killed for up to three months following an application of fipronil. If, however, your dog or puppy is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply LC-2010-2 [or other approved alternate brand name] For Dogs for thirty (30) days.

Please note that there is no need to reapply following your dog's exposure to bathing or water immersion, as LC-2010-2 [or other approved alternate brand name] For Dogs remains effective in those conditions.

Storage and Disposal

Do not contaminate water food, or feed by storage or disposal.

Storage. Store unused application pipettes in the original child-resistant container and outer box only, out of reach of children and animals.

Pesticide Disposal. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Container Disposal. Nonrefillable container. **If empty:** Do not reuse this container. Place in trash or offer for recycling if available.

First Aid

Have the product container or label with you when calling a poison control center or doctor, or if going for treatment.

If Swallowed: Immediately call a poison control center or doctor for treatment advice. Have the person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

If on Skin: Rinse skin with plenty of soap and water. Get medical attention if irritation persists.

PRECAUTIONARY STATEMENTS

Hazards to Humans. Caution.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Hazards to Domestic Animals.

For external use only. Do not use on puppies under 8 weeks of age. Sensitivities may occur after using ANY pesticide product for pets. While temporary irritation at the application area may occur, if signs of continued sensitivity occur, consult a veterinarian immediately. Should any unusual reactions to the application occur, do not reapply before consulting with a veterinarian. Certain medications can interact with pesticides. Consult with your veterinarian before using this product on medicated, debilitated, or aged dogs. Call 1-888-908-TICK for 24-hour assistance.

Physical or Chemical Hazards

Flammable: Keep away from heat and open flame.

Application Options for Different Sizes of Dogs

LC-2010-2 [or other approved alternate brand name] For Dogs comes in four different packages for different-sized dogs and puppies eight (8) weeks or older:

- * Up to 22 lbs.
- * 23 to 44 lbs.
- * 45 to 88 lbs.
- * 89 to 132 lbs.

Warranty

To the extent consistent with applicable law, Sellers make no warranty, express or implied, concerning the use of this product other than as indicated on the labeling. Buyer assumes all risk of use and handling of the product when such use and handling are contrary to the label instructions.

* This product is not manufactured or distributed by Merial, the makers of Frontline® Top Spot

LoradoChem, Inc.
Circa Center, 12th Floor
2929 Arch Street
Philadelphia, PA 18104-2891 USA

EPA Reg. No. 86230-E
Or

EPA Est. No. 87688-IND-01

©2010 LoradoChem, Inc. All rights reserved.

(Drawing of telephone receiver) Questions? Comments?
1-888-908-TICK

Made in India

Sublabel C: Labeling on the Child Resistant Package

Top of lidding foil: Dotted line with representation of a scissors

Company Name: LoradoChem

Product Name: LC-2010-2 [or other approved alternate brand name]
Fipronil For Dogs

Graphic picture of the pipette

Instructions: **To Open Package:**
Cut across the top
as shown.
Peel down the foil
completely before
removing pipette.

Species and amount: [Dogs up to 22 lbs. – 0.023 fl.oz.]
Or
[Dogs 23-44 lbs. – 0.045 fl.oz.]
Or
[Dogs 45-88 lbs. – 0.091 fl.oz.]
Or
[Dogs 89-132 lbs. – 0.136 fl.oz.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

Lot number: Lot No: XXXX

Sublabel D: Labeling on the Pipette

Neck of pipette: Contains: fipronil (9.7%)

Body of pipette: **LoradoChem**
 [0.023 fl.oz.]
 Or
 [0.0045 fl.oz.]
 Or
 [0.091 fl.oz.]
 Or
 [0.136 fl.oz.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

LC-2010-2 [or other approved alternate brand name]
FIPRONIL For Dogs

[For Dogs up to 22 lbs.]
Or
[For Dogs 23-44 lbs.]
Or
[For Dogs 45-88 lbs.]
Or
[For Dogs 89-132 lbs.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

KEEP OUT OF REACH OF CHILDREN

CAUTION

See package insert for directions for use.

EPA Reg. No. 86230-E

Sublabel E: Stickers for Re-application Reminders

LC-2010-2
[or other approved alternate brand name]
Fipronil for Dogs
Care Card

Kills Fleas, Ticks, Chewing Lice, & Mosquitoes

Picture of Dog

Month 1

Drawing of paw
<hr/>
Date of Application

Month 2

Drawing of paw
<hr/>
Date of Application

Month 3

Drawing of paw
<hr/>
Date of Application

Place sticker on your calendar or refrigerator to remind yourself to apply LC-2010-2 [or other approved alternate brand name] For Dogs to your dog

Pet's Name: _____ lbs.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 86230-2	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) LoradoChem Inc. LC-2010-2 Fipronil for Dogs	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) LoradoChem Inc., Cira Centre, 12th Floor, 22929 Arch Street, Philadelphia, PA 16104-2871 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated Jan. 10, 2011
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) cardboard	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Iain Weatherston		Title Senior Managing Consultant		Telephone No. (Include Area Code) (623)-535-4360	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Senior Managing Consultant			
4. Typed Name Iain Weatherston		5. Date January 19, 2011			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 31, 2010

NOTE TO RM 10 Richard Gebken

SUBJECT: Resubmission of Data for Child-Resistant Packaging EPA FILE NO:
86230-R, 86230-E, 86230-G, 86230-U, DP 376304, 376314, 376335, &
376342 Decision # 429282, 429489, 429492, & 429493

Please note that for EPA FILE NO: 86230-R, 86230-E, 86230-G, and 86230-U the 8 Senior Adult Use Effectiveness (SAUE) data are inconclusive. The registrant will need to submit 8 revised SAUE studies or 16 new studies (8 senior and 8 child studies) for review. It will require review of the raw data and supporting documentation for each of the new/revised studies (see Summary of Findings in review). These new/revised studies will require the same resource intensive activity of approximately 150 days (5 months) once the reviewer receives the aforementioned submission. Please advise registrant accordingly.

Thank you for your cooperation in this matter. If you have any questions please contact me at (703)-308-7368.

A handwritten signature in cursive script, reading "Rosalind L. Gross", is located in the bottom right area of the page.

Rosalind L. Gross

CHILD-RESISTANT PACKAGING REVIEW
Technical Review Branch

IN 04/13/2010 OUT 08/26/2010

RD, TRB, Reviewed by Rosalind L. Gross 08/26/2010

EPA Reg. No. or File Symbol 86230-R & 86230-E

DP Barcode 376304 & 376314

Decision # 429282 & 429489

EPA Petition or EUP No. _____

Date Division Received 3/2/10 & 3/5/10

Type Product(s) Insecticide (flea product)

Data Accession No(s). MRID numbers 480057-02 & 03, 480130-05, 03, 06, 04,
07, & 02,

Product Mgr./Chemical Review Mgr./Contact Person RM 10
Division RD

Product Name(s) LC-2010-1 Fipronil For Cats LC-2010-2 Fipronil For Dogs

Company Name(s) LoradoChem Inc.

Submission Purpose Review of CRP studies to determine if they are
adequate to support CRP certification for 5 different
pipette sizes in purple and teal for 4 different dog and
cat products

Active Ingredient(s), PC code, & % Fipronil 9.7%

Summary of Findings

In conclusion all the requirements for CRP have not been met for EPA Reg. No. 86230-R, 86230-E, 86230-G, and 86230-U. For the details of each study refer to the attached summary chart (summarycht86230-1,2,3,4.doc).

The 8 Senior Adult Use Effectiveness (SAUE) studies are

inconclusive as submitted. The comments on the raw data sheets (such as cut top pipette, cut top stem, cut applicator, cut into pipette, water leaking into cavity before she opened) are vague. Additional clarifications consisting of an explanation and photographs are necessary to allow the Agency to determine whether or not these packages should be considered successfully opened. In accordance with 16 CFR 1700.20 and the EPA website the Agency will consider a package successfully "opened" in SAUE testing only if the contents of the package can be removed in a condition suitable for their intended use, and the process of opening and removing the contents would not result in significant exposure to the pesticide. This means that any breaks and cuts in the pipette that have the potential to release the contents (such as cutting into the hollow/liquid-containing part of the pipette stem) would be counted as a Senior Adult Use Effectiveness (SAUE) test failure.

The registrant can reevaluate the raw data sheets against the actual test packages to determine whether or not the packages should be considered successfully opened as per the aforementioned criteria. Note the comments on the raw data sheets need to be reasonably reconciled with the explanation and photographs of the test packages to allow the Agency to determine whether or not these packages should be considered successfully opened. In the case of the "water leaking into cavity before she opened", if the registrant maintains this is a defective package then the subject should be replaced. The new subject should be of the same age and sex category and meet tester and testing site percentage requirements per 16 CFR 1700.20. The test package should be checked pretesting to make sure it is not defective. **The studies may then be resubmitted with the all the raw data sheets, explanations, and photographs where necessary.** If the reported SAUE has changed from the initial submission or the raw data has changed a revised electronic version is requested.

Note the CRP certifications are not supported by any CRP test data for the 0.023 fl. oz. size for EPA Reg. No. 86230-E and 86230-U. The directions on opening the package given to consumers must be identical to those given to the seniors during testing for the blisters. The senior testing directions must be on the back of each blister and the labels must refer the consumer to the back of the blister (CRP) per the labels submitted April 21, 2010 for EPA Reg. No. 86230-R and 86230-E and June 1, 2010 for EPA Reg. No. 86230-G and 86230-U. The labels submitted April 21, 2010 for EPA Reg. No. 86230-R and 86230-E need to be corrected in the storage section of the label statement to read "Store unused application pipettes in the original unopened child-resistant container and....". The labels submitted June 1, 2010 for EPA Reg. No. 86230-G and 86230-U need to be corrected in the storage section of the label statement to read "Store unused application pipettes in the original unopened child-resistant container and....". The final label must show pipette sizes labeled in fl. oz. The number of ml on the label should be based on [29.6ml per fl. oz. x number of fl. oz. on the pipettes]. Should any

human experience/epidemiological evidence indicate a problem once the product is in the marketplace, the Agency reserves the right to reexamine this data comprehensively and to question the child resistance of the package involved.

Package

The package consists of a pipette containing the product inside a blister. There are 3 blisters connected to each other per card. The blister, which is the child-resistant package, is opened by the directions on the back of the blister. These directions indicate: to cut across the top of the blister along a dotted line with a scissors icon; peel down the foil on the back of the blister completely; and then remove the pipette. The pipettes are purple for the Fipronil only products EPA Reg. No. 86230-R and EPA Reg. No. 86230-E. The pipettes are teal for the Fipronil and S-Methoprene products EPA Reg. No. 86230-G and EPA Reg. No. 86230-U. The pipette comes in 5 different sizes (0.017, 0.023, 0.045, 0.91, and .136 fl. oz.).

Toxicity

The toxicity of the product is based on the toxicity of Fipronil. The toxic or harmful amount of Fipronil for an 11.4 kg child is 2.5mg/kg times 11.4kg, which equals 28.5mg. Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1028mg/ml x 0.097 Fipronil] = 0.286ml = **0.29ml for Fipronil only products EPA Reg. No. 86230-R, 86230-E.** Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1022.3mg/ml x 0.098 Fipronil] = 0.284ml = **0.28ml for Fipronil & S-Methoprene Cat EPA Reg. No. 86230-G.** Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1020mg/ml x 0.098 Fipronil] = 0.285ml = **0.29ml for Fipronil & S-Methoprene Dog EPA Reg. No. 86230-U.** Access to one pipette represents a failure for a child for all sizes greater than 0.28ml for EPA Reg. No. 86230-G, or 0.29ml for EPA Reg. No. 86230-R, 86230-E, and 86230-U.

Toxicity, Child Failure, and Package

EPA Reg #	Fl. Oz.	ml (29.6ml =1 fl.oz)	Product Density mg/ml	% Fipronil	mg Fipronil	# unit = tox /harmful amt

EPA Reg #	Fl. Oz.	ml (29.6ml =1 fl.oz)	Product Density mg/ml	% Fipronil	mg Fipronil	# unit = tox /harmful amt
86230-R cat Fipronil	0.017	0.5	1028	9.7	49.86	1
86230-E dog Fipronil	0.023	0.68	1028	9.7	67.81	1
86230-E dog Fipronil	0.045	1.33	1028	9.7	132.62	1
86230-E dog Fipronil	0.091	2.69	1028	9.7	268.24	1
86230-E dog Fipronil	0.136	4.03	1028	9.7	401.86	1
86230-G cat Fipronil & S- Methoprene	0.017	0.5	1022.3	9.8	50.09	1
86230-U dog Fipronil & S- Methoprene	0.023	0.68	1020	9.8	67.97	1

EPA Reg #	Fl. Oz.	ml (29.6ml =1 fl.oz)	Product Density mg/ml	% Fipronil	mg Fipronil	# unit = tox /harmful amt
86230-U dog Fipronil & S- Methoprene	0.045	1.33	1020	9.8	132.95	1
86230-U dog Fipronil & S- Methoprene	0.091	2.69	1020	9.8	268.89	1
86230-U dog Fipronil & S- Methoprene	0.136	4.03	1020	9.8	402.84	1

Failure

For the purposes of CRP testing **a child failure** is access to one blister for all sizes greater than 0.28ml for EPA Reg. No. 86230-G, or 0.29ml for EPA Reg. No. 86230-R, 86230-E, and 86230-U.

A unit failure for the child test was defined as access to the pipette or any partial or complete access to the placebo (water) for EPA Reg. No. 86230-R, 86230-E, 86230-G, and 86230-U.

A Senior Adult Use Effectiveness failure is the inability to access the pipette in the prescribed test time of 5 minutes for the first package or 1 minute for the second package, breaking or cutting the pipette that has the potential to release the contents (such as cutting into the hollow/liquid-containing part of the pipette stem) in the prescribed test time of 5 minutes for the first package or 1 minute for the second package, or accessing any amount of placebo (water) while opening the blister in the prescribed test time of 5 minutes for the first package or 1 minute for the second package.

Analysis of Data and Conclusion

The CRP certifications dated February 25, 2010 for EPA Reg. No. 86230-R, 86230-E, 86230-G, and 86230-U are acceptable. **Note** the CRP certifications are not supported by any CRP test data for the **0.023 fl. oz. size** for EPA Reg. No. 86230-E and 86230-U. The **labels submitted April 21, 2010** for EPA Reg. No. 86230-R and 86230-E **need to be corrected** in the storage section of the label statement to read "Store unused application pipettes in the original **unopened** child-resistant container and....". The **labels submitted June 1, 2010** for EPA Reg. No. 86230-G and 86230-U **need to be corrected** in the storage section of the label statement to read "Store unused application pipettes in the original **unopened** child-resistant container and....".

A screening of CRP studies (MRID numbers 480057-02 & 03, 480130-05, 03, 06, 04, 07, & 02, 480132-02 & 03, 480131-06, 03, 05, 04, 07, & 02) revealed the CRP studies associated with the lowest senior adult use effectiveness (SAUE) was MRID number 480130-02 and the lowest child-resistant effectiveness (CRE) was MRID number 480057-02. A **comprehensive** review was done for the lowest SAUE including the CRE associated with it (MRID numbers 480130-02 & 480130-07) and the lowest CRE including the SAUE associated with it (MRID numbers 480057-02 & 480057-03). On the basis of the comprehensive review for the SAUE studies MRID numbers 480130-02 & 480057-03 the other 6 SAUE studies were also comprehensively reviewed. **Note** the 6 remaining CRE studies were not comprehensively reviewed.

Child Study 3 purple pipettes each in a blister 0.017 fl. oz. size (MRID 480057-02 which is the lowest CRE) involved giving each child 1 card with 3 blisters each containing a pipette with 0.017 fl. oz. of water at the start of the test. A child failure was defined as access to 1 blister as the blister was the child-resistant feature. A blister failure was access to the pipette or any partial or complete access to the placebo. **Data Analysis** showed 1 age calculation error, a 46 month old female was reported as 47 months old, but the child remains in same age group. The results are not affected. There were 4 child failures, two 50 month old males, a 47 month old female, and a 49 month old female. One 50 month old male accessed 2 pipettes and the other three subjects each accessed 1 pipette. **Study is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.**

Senior Adult Use Effectiveness Study 3 purple pipettes each in a blister 0.017 fl. oz. size (MRID 480057-03) involved having the test subjects open one blister during a 5 minute test period and a one minute test period. Scissors were made available during testing because the test directions given to the seniors called for their use. A Senior Adult Use Effectiveness failure is failure to access the pipette in the prescribed test time of 5 minute for the first package or 1 minute for the second package, breaking or cutting the pipette that has the potential to release the contents (such as cutting into the hollow/liquid-containing part of the pipette stem) in the prescribed test time of 5 minute for the first

package or 1 minute for the second package, or accessing any amount of placebo/water while opening the blister in the prescribed test time of 5 minute for the first package or 1 minute for the second package. **Review of the comments on the raw data sheets** indicated 4 subjects whose results were **inconclusive**. Additional clarifications consisting of an explanation and photographs (test packages) are necessary to allow the Agency to determine whether or not these packages should be considered successfully opened. These 4 subjects are a 54 year old male package 18, a 55 year old male package 46, a 57 year old male package 45, and a 69 year old female package 80. **Data Analysis** showed 7 senior failures, (a 54 year old female and 64 year old female failed to open package A, a 54 year old female, a 60 year old female, a 68 year old male, a 69 year old female, and a 70 year old female failed to open package B). **In conclusion results are inconclusive. CRP SAUE requirements are not met.**

Child Study 3 purple pipettes each in a blister 0.136 fl. oz. size (MRID 480130-07) involved giving each child 1 card with 3 blisters each containing a pipette with 0.136 fl. oz. of water at the start of the test. A child failure was defined as access to 1 blister as the blister was the child-resistant feature. A blister failure was access to the pipette or any partial or complete access to the placebo. **Data Analysis** showed 2 age calculation errors, a 49 month old female was reported as 50 months old, and a 45 month old male was reported as 46 months old. The children remained in the same age group. The results are not affected. There were 2 child failures, a 47month old female accessed 1 pipette and a 50 month old female accessed 2 pipettes. **Study is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.**

Senior Adult Use Effectiveness Study 3 purple pipettes each in a blister 0.136 fl. oz. size (MRID 480130-02 which is the lowest SAUE) involved having the test subjects open one blister during a 5 minute test period and a one minute test period. Scissors were made available during testing because the test directions given to the seniors called for their use. A Senior Adult Use Effectiveness failure is failure to access the pipette in the prescribed test time of 5 minute for the first package or 1 minute for the second package, breaking or cutting the pipette that has the potential to release the contents (such as cutting into the hollow/liquid-containing part of the pipette stem) in the prescribed test time of 5 minute for the first package or 1 minute for the second package, or accessing any amount of placebo/water while opening the blister in the prescribed test time of 5 minute for the first package or 1 minute for the second package. **Review of the comments on the raw data sheets** indicated 4 subjects whose results were inconclusive. Additional clarifications consisting of an explanation and photographs (test packages) are necessary to allow the Agency to determine whether or not these packages should be considered successfully opened. These 4 subjects are a 61 year old female package 57, a 63 year old female package 71, a 60 year old male package 86, and a 61 year old male package 99. **Data Analysis** demonstrated errors in the electronic version due to inputting package 55 twice. A new electronic version was

submitted. Data Analysis of it showed one age calculation error, a 54 year old male was reported as 51 years old but subject remains in same age group. The results are not affected. There were 10 senior failures, (a 56 year old female, two 57 year old females, two 62 year old females, a 66 year old female, a 68 year old female, a 68 year old male, a 69 year old female, and a 70 year old female failed to open package B). **In conclusion results are inconclusive. CRP SAUE requirements are not met.**

Senior Adult Use Effectiveness Study 3 purple pipettes each in a blister 0.045 fl. oz. size (MRID 480130-03) involved having the test subjects open one blister during a 5 minute test period and a one minute test period. Scissors were made available during testing because the test directions given to the seniors called for their use. A Senior Adult Use Effectiveness failure is failure to access the pipette in the prescribed test time of 5 minute for the first package or 1 minute for the second package, breaking or cutting the pipette that has the potential to release the contents (such as cutting into the hollow/liquid-containing part of the pipette stem) in the prescribed test time of 5 minute for the first package or 1 minute for the second package, or accessing any amount of placebo/water while opening the blister in the prescribed test time of 5 minute for the first package or 1 minute for the second package. **Review of the comments on the raw data sheets** was inconclusive **because 75 of the raw data sheets were not submitted.** Comments on the raw data sheets (such as cut top pipette, cut top stem, cut applicator, cut into pipette) are vague. Additional clarifications consisting of an explanation and photographs (test packages) may be necessary to allow the Agency to determine whether or not these packages should be considered successfully opened. In accordance with 16 CFR 1700.20 and the EPA website the Agency will consider a package successfully "opened" in SAUE testing only if the contents of the package can be removed in a condition suitable for their intended use, and the process of opening and removing the contents would not result in significant exposure to the pesticide. This means that any breaks and cuts in the pipette that have the potential to release the contents (such as cutting into the hollow/liquid-containing part of the pipette stem) would be counted as a Senior Adult Use Effectiveness (SAUE) failure. The registrant can reevaluate the raw data sheets for this study against the actual test packages to determine whether or not the packages should be considered successfully opened as per the aforementioned criteria. **Note** the comments on the raw data sheets need to be reasonably reconciled with the explanation and photographs of the test packages to allow the Agency to determine whether or not these packages should be considered successfully opened. **Data Analysis** showed one age calculation error a 54 year old female [test date 2/13/10 birth date 10/6/55] was reported as 55 years old which means **the age distribution is not in accordance with 16 CFR 1700.20.** There were 5 senior failures, (a 53 year old female failed to open package A, a 52 year old female, a 59 year old female, a 62 year old male, and a 63 year old female failed to open package B). **In conclusion results are inconclusive. CRP SAUE requirements are not met.**

Senior Adult Use Effectiveness Study 3 purple pipettes each in a blister 0.091 fl. oz. size (MRID 480130-04) involved having the test subjects open one blister during a 5 minute test period and a one minute test period. Scissors were made available during testing because the test directions given to the seniors called for their use. A Senior Adult Use Effectiveness failure is failure to access the pipette in the prescribed test time of 5 minute for the first package or 1 minute for the second package, breaking or cutting the pipette that has the potential to release the contents (such as cutting into the hollow/liquid-containing part of the pipette stem) in the prescribed test time of 5 minute for the first package or 1 minute for the second package, or accessing any amount of placebo/water while opening the blister in the prescribed test time of 5 minute for the first package or 1 minute for the second package. **Review of the comments on the raw data sheets** indicated 6 subjects whose results were inconclusive. Additional clarifications consisting of an explanation and photographs (test packages) are necessary to allow the Agency to determine whether or not these packages should be considered successfully opened. These 6 subjects are a 52 year old female package 1, a 54 year old female package 15, a 55 year old male package 44, a 56 year old male package 48, a 61 year old female package 54, and a 67 year old female package 80. **Data Analysis** showed one age calculation error, a 68 year old female was reported as 67 years old but the subject remains in same age group. The results are not affected. There were 3 senior failures, (a 60 year old male, a 61 year old female, and a 70 year old male failed to open package B). **In conclusion results are inconclusive. CRP SAUE requirements are not met.**

Senior Adult Use Effectiveness Study 3 teal pipettes each in a blister 0.017 fl. oz. size (MRID 480132-03) involved having the test subjects open one blister during a 5 minute test period and a one minute test period. Scissors were made available during testing because the test directions given to the seniors called for their use. A Senior Adult Use Effectiveness failure is failure to access the pipette in the prescribed test time of 5 minute for the first package or 1 minute for the second package, breaking or cutting the pipette that has the potential to release the contents (such as cutting into the hollow/liquid-containing part of the pipette stem) in the prescribed test time of 5 minute for the first package or 1 minute for the second package, or accessing any amount of placebo/water while opening the blister in the prescribed test time of 5 minute for the first package or 1 minute for the second package. **Review of the comments on the raw data sheets** indicated 4 subjects whose results were inconclusive. Additional clarifications consisting of an explanation and photographs (test packages) are necessary to allow the Agency to determine whether or not these packages should be considered successfully opened. These 4 subjects are a 54 year old female package 14, a 63 year old female package 64, a 68 year old female package 80, and a 61 year old female package 83. **Data Analysis** demonstrated errors in the electronic version due to inputting a 58 year old male as 49 years old. The second electronic version also had errors due to input the opening time

for package 7 (package B) a failure as 39 seconds not 61 seconds. A new electronic version was submitted. Data Analysis of it showed 10 senior failures, (a 68 year old female failed to open package A, a 53 year old female, a 54 year old female, a 58 year old female, a 59 year old female, a 62 year old male, a 63 year old female, a 64 year old female, a 67 year old female and a 68 year old male failed to open package B). **In conclusion results are inconclusive. CRP SAUE requirements are not met.**

Senior Adult Use Effectiveness Study 3 teal pipettes each in a blister 0.045 fl. oz. size (MRID 480131-03) involved having the test subjects open one blister during a 5 minute test period and a one minute test period. Scissors were made available during testing because the test directions given to the seniors called for their use. A Senior Adult Use Effectiveness failure is failure to access the pipette in the prescribed test time of 5 minute for the first package or 1 minute for the second package, breaking or cutting the pipette that has the potential to release the contents (such as cutting into the hollow/liquid-containing part of the pipette stem) in the prescribed test time of 5 minute for the first package or 1 minute for the second package, or accessing any amount of placebo/water while opening the blister in the prescribed test time of 5 minute for the first package or 1 minute for the second package. **Review of the comments on the raw data sheets** indicated 8 subjects whose results were inconclusive. Additional clarifications consisting of an explanation and photographs (test packages) are necessary to allow the Agency to determine whether or not these packages should be considered successfully opened. **Note** the comments on the raw data sheets need to be reasonably reconciled with the explanation and photographs of the test packages to allow the Agency to determine whether or not these packages should be considered successfully opened. These 8 subjects are a 54 year old female package 14, a 53 year old male package 20, a 51 year old male package 24, a 59 year old female package 26, a 58 year old female package 43, a 64 year old female package 82, a 68 year old male package 87, and a 61 year old male package 92. **Data Analysis** demonstrated errors in the electronic version due to inputting package 71 twice. A new electronic version was submitted. Data Analysis of it showed 6 senior failures, (a 51 year old female, two 63 year old females, a 66 year old male, a 66 year old female, and a 69 year old female failed to open package B). **In conclusion results are inconclusive. CRP SAUE requirements are not met.**

Senior Adult Use Effectiveness Study 3 teal pipettes each in a blister 0.091 fl. oz. size (MRID 480131-04) involved having the test subjects open one blister during a 5 minute test period and a one minute test period. Scissors were made available during testing because the test directions given to the seniors called for their use. A Senior Adult Use Effectiveness failure is failure to access the pipette in the prescribed test time of 5 minute for the first package or 1 minute for the second package, breaking or cutting the pipette that has the potential to release the contents (such as cutting into the hollow/liquid-containing part of the pipette stem) in the prescribed test time of 5 minute for the first package or 1

minute for the second package, or accessing any amount of placebo/water while opening the blister in the prescribed test time of 5 minute for the first package or 1 minute for the second package. **Review of the comments on the raw data sheets** indicated 3 subjects whose results were inconclusive. Additional clarifications consisting of an explanation and photographs (test packages) are necessary to allow the Agency to determine whether or not these packages should be considered successfully opened. These 3 subjects are a 58 year old female package 27, a 64 year old female package 52, and a 66 year old female package 77. In the case of the “**water leaking into cavity before she opened**”, if the registrant maintains this is a defective package then the subject should be replaced. The new subject should be of the same age and sex category and meet tester and testing site percentage requirements per 16 CFR 1700.20. The test package should be checked pretesting to make sure it is not defective. **Data Analysis** showed 1 age calculation error, a 61 year old female was reported as 67 years old. Subject remains in same age group, so results are not affected. There were 8 senior failures, (a 56 year old female failed to open package A, a 52 year old female, a 61 year old male, two 62 year old females, two 63 year old females, and a 69 year old female failed to open package B). **In conclusion results are inconclusive. CRP SAUE requirements are not met.**

Senior Adult Use Effectiveness Study 3 teal pipettes each in a blister 0.136 fl. oz. size (MRID 480131-02) involved having the test subjects open one blister during a 5 minute test period and a one minute test period. Scissors were made available during testing because the test directions given to the seniors called for their use. A Senior Adult Use Effectiveness failure is failure to access the pipette in the prescribed test time of 5 minute for the first package or 1 minute for the second package, breaking or cutting the pipette that has the potential to release the contents (such as cutting into the hollow/liquid-containing part of the pipette stem) in the prescribed test time of 5 minute for the first package or 1 minute for the second package, or accessing any amount of placebo/water while opening the blister in the prescribed test time of 5 minute for the first package or 1 minute for the second package. **Review of the comments on the raw data sheets** indicated 4 subjects whose results were inconclusive. Additional clarifications consisting of an explanation and photographs (test packages) are necessary to allow the Agency to determine whether or not these packages should be considered successfully opened. These 4 subjects are a 51 year old female package 27, a 57 year old female package 39, a 63 year old female package 62, and a 61 year old male package 95. **Data Analysis** showed 5 senior failures, (a 55 year old female, two 68 year old females, a 69 year old female, and a 70 year old female failed to open package B). **In conclusion results are inconclusive. CRP SAUE requirements are not met.**

Based on the CRE values the registrant reported for MRID numbers 480130-05 & 06, 480132-02, 480131-06, 05, & 07 along with a computerized analysis of the data these studies pass the CRE sequential test chart in 16 CFR 1700.20. **For the details of each study refer to the attached summary chart**

(summarycht86230-1,2,3,4.doc).

In conclusion all the requirements for CRP have not been met for EPA Reg. No. 86230-R, 86230-E, 86230-G, and 86230-U. For the details of each study refer to the attached summary chart (summarycht86230-1,2,3,4.doc). The 8 SAUE studies are inconclusive as submitted. The comments on the raw data sheets (such as cut top pipette, cut top stem, cut applicator, cut into pipette, water leaking into cavity before she opened) are vague. Additional clarifications consisting of an explanation and photographs are necessary to allow the Agency to determine whether or not these packages should be considered successfully opened. In accordance with 16 CFR 1700.20 and the EPA website the Agency will consider a package successfully "opened" in SAUE testing only if the contents of the package can be removed in a condition suitable for their intended use, and the process of opening and removing the contents would not result in significant exposure to the pesticide. This means that any breaks and cuts in the pipette that have the potential to release the contents (such as cutting into the hollow/liquid-containing part of the pipette stem) would be counted as a Senior Adult Use Effectiveness test failure.

The registrant can reevaluate the raw data sheets against the actual test packages to determine whether or not the packages should be considered successfully opened as per the aforementioned criteria. Note the comments on the raw data sheets need to be reasonably reconciled with the explanation and photographs of the test packages to allow the Agency to determine whether or not these packages should be considered successfully opened. In the case of the "water leaking into cavity before she opened", if the registrant maintains this is a defective package then the subject should be replaced. The new subject should be of the same age and sex category and meet tester and testing site percentage requirements per 16 CFR 1700.20. The test package should be checked pretesting to make sure it is not defective. **The studies may then be resubmitted with the all the raw data sheets, explanations, and photographs where necessary. If the reported SAUE has changed from the initial submission or the raw data has changed a revised electronic version is requested.**

Note the CRP certifications are not supported by any CRP test data for the 0.023 fl. oz. size for EPA Reg. No. 86230-E and 86230-U. The directions on opening the package given to consumers must be identical to those given to the seniors during testing for the blisters. The senior testing directions must be on the back of each blister and the labels must refer the consumer to the back of the blister (CRP) per the labels submitted April 21, 2010 for EPA Reg. No. 86230-R and 86230-E and June 1, 2010 for EPA Reg. No. 86230-G and 86230-U. The labels submitted April 21, 2010 for EPA Reg. No. 86230-R and 86230-E need to be corrected in the storage section of the label statement to read "Store unused application pipettes in the original unopened child-resistant container and....". The labels submitted June 1, 2010

for EPA Reg. No. 86230-G and 86230-U need to be corrected in the storage section of the label statement to read "Store unused application pipettes in the original **unopened child-resistant container and....". The final label must show pipette sizes labeled in fl. oz. The number of ml on the label should be based on [29.6ml per fl. oz. x number of fl. oz. on the pipettes]. Should any human experience/epidemiological evidence indicate a problem once the product is in the marketplace, the Agency reserves the right to reexamine this data comprehensively and to question the child resistance of the package involved.**

July 22, 2010

CRPdatasummarycht

EPA REG # 86230-R LC-2010-1 Fipronil For Cats and 86230-E LC-2010-2 Fipronil For Dogs

Chemical - Fipronil 9.7%

Company Name Lorado Chem Inc.

A **Senior Adult Use Effectiveness failure** is failure to access the pipette in the prescribed test time of 5 min. for the 1st pkg or 1 min. for the 2nd pkg, breaking or cutting the pipette that has the potential to release the contents (such as cutting into the hollow/liquid-containing part of the pipette stem) in the prescribed test time of 5 min. for the 1st pkg or 1 min. for the 2nd pkg, or accessing any amount of placebo/water while opening the blister in the prescribed test time of 5 min. for the 1st pkg or 1 min. for the 2nd pkg.

A **child failure** is access to 1 unit. Access to 1 unit is more than 28.5mg of Fipronil for all sizes.

A **unit failure** is access to the pipette or any partial or complete access to the placebo (water).

Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1028mg/ml x 0.097 Fipronil] = 0.286ml = **0.29ml for Fipronil only products**

Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1022.3mg/ml x 0.098 Fipronil] = .284ml = **0.28ml for Fipronil & S-Methoprene Cat**

Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1020mg/ml x 0.098 Fipronil] = 0.285ml = **0.29ml for Fipronil & S-Methoprene Dog**

% AI - Fipronil 9.7%

Note:

1. The blister is the child-resistant feature.
2. The pipettes are filled in fl. oz. (5/26/10 telephone call R. Gross/D. Petrick). The pipette sizes in ml are based on [29.6ml per fl. oz. x number of fl. oz. on the pipettes]. The final label must show pipette sizes labeled in fl. oz. The number of ml on label should be based on [29.6ml per fl. oz. x number of fl. oz. on the pipettes].
3. 16 CRP studies were submitted by the Company to cover the 5 sizes (0.017, 0.023, 0.045, 0.091, and 0.136 fl. oz.) in 2 colors (purple and teal). No studies were submitted for the 0.023 fl. oz. size in either color. No extrapolation was allowed. In the purple color the 0.017 fl. oz. size (MRID 480057-02) 4 child failures were reported by the company, which is a pass of the 50 child test in 16 CFR 1700.20. However, it is a marginal pass as 5 child failures is the maximum for a 50 child pass in 16 CFR 1700.20. Therefore, it will not be used for extrapolation purposes. In the teal color the 0.017 fl. oz. size (MRID 480132-03) a 90% Senior Adult Use Effectiveness (SAUE) was reported by the company, which is a marginal pass of the SAUE per 16 CFR 1700.15(b)(2)(i) per the protocol in 16 CFR 1700.20. Therefore, it will not be used for extrapolation purposes.

EPA REG #	MRID	PKG Description Include ml per Pkg # unit/pkg, child fail = # units, color, tox/harm = # units	# Pkges Child Get at Begin Test	Company Data		Data		Conclusion include CRE & SAUE via computer analysis
				CRE	SAUE	Comprehens ive Review & why	Only Comp uter Analy sis	
86230-E dog Fipronil		purple pipette @ 0.023 fl. oz. (0.68ml) in a blister and three blisters attached to each other as a card. Water placebo in pipette. Tox/harm = 1 pipette, child fail = 1 pipette	1 card with 3 blisters					Study not done. Cannot extrapolate based on 0.5ml MRID (480057-02 & 480057-03) and 1.33ml size MRID (480130-05 & 480130-03)
86230-E dog Fipronil	480130-05 GLM 29090	purple pipette @ 0.045 fl. oz. (1.33ml) in a blister and three blisters attached to each other as a card. Water placebo in pipette. Tox/harm = 1 pipette, child fail = 1 pipette	1 card with 3 blisters	2 child failures = Pass 50 child test. 1 child open 3 blister, 1 child open 1 blister.			X	CRP certification dated 2/25/10 is ok. Label submitted 4/21/2010 page 9 label on CRP has same CRP directions as in study, label on box and pkg insert refer consumer to back of CRP for opening directions. Note this is acceptable. However in the storage section of the label the statement should be changed to read "Store unused application pipettes in the original unopened child-resistant container and...." Data Analysis showed 1 age calculation error, a 42 month old male was reported as a 43 month old, but subject remains in same age group. Results are not affected. There were 2 child failures, a 49 month old male, and a 51 month old male. One male accessed 3 pipettes and the other male accessed 1 pipette. Study is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.

EPA REG #	MRID	PKG Description Include ml per Pkg # unit/pkg, child fail = # units, color, tox/harm = # units	# Pkges Child Get at Begin Test	Company Data		Data		Conclusion include CRE & SAUE via computer analysis
				CRE	SAUE	Comprehensive Review & why	Only Computer Analysis	
86230-E dog Fipronil	480130-06 GLM 29092	purple pipette @ 0.091 fl. oz. (2.69ml) in a blister and three blisters attached to each other as a card. Water placebo in pipette. Tox/harm = 1 pipette, child fail = 1 pipette	1 card with 3 blisters	no child failures = Pass 50 child test.			X	CRP certification dated 2/25/10 is ok. Label submitted 4/21/2010 page 9 label on CRP has same CRP directions as in study, label on box and pkg insert refer consumer to back of CRP for opening directions. Note this is acceptable. However in the storage section of the label the statement should be changed to read "Store unused application pipettes in the original unopened child-resistant container and...." Data Analysis showed 1 age calculation error, a 50 month old female was reported as a 51 month old, but subject remains in same age group. Results are not affected. There were no child failures. Study is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.
86230-E dog Fipronil	480130-04 GLM 10057	purple pipette @ 0.091 fl. oz. (2.69ml) in a blister and three blisters attached to each other as a card. Water placebo in pipette. Tox/harm = 1 pipette, child fail = 1 pipette	1 card with 3 blisters		97% SAUE 3 Fail = 3 Fail open pkg B	X ? SAUE per raw data sheet comments		CRP certification dated 2/25/10 is ok. Label submitted 4/21/2010 page 9 label on CRP has same CRP directions as in study, label on box and pkg insert refer consumer to back of CRP for opening directions. Note this is acceptable. However in the storage section of the label the statement should be changed to read "Store unused application pipettes in the original unopened child-resistant container and...." Review of the comments on the raw data sheets indicated 6 subjects whose results were inconclusive. Additional clarifications consisting of an explanation and photographs(test packages) are necessary to allow the Agency to determine whether or not these packages should be considered successfully opened. These 6 subjects are a 52 year old female package 1, a 54 year old female package 15, a 55 year old male package 44, a 56 year old male package 48, a 61 year old female package 54, and a 67 year old female package 80. Data Analysis showed one age calculation error, a 68 year old female was reported as 67 years old but subject remains in same age group. Results are not affected. There were 3 senior failures, (a 60 year old male, a 61 year old female, and a 70 year old male failed to open package B). In conclusion results are inconclusive. CRP SAUE requirements are not met.

July 22, 2010

CRPdatasummarycht

EPA REG # 86230-G LC-2010-3 Plus Fipronil & S-Methoprene For Cats

Chemical - Fipronil 9.8%
S-Methoprene 11.8%

Company Name Lorado Chem Inc.

A **Senior Adult Use Effectiveness failure** is failure to access the pipette in the prescribed test time of 5 min. for the 1st pkg or 1 min. for the 2nd pkg, breaking or cutting the pipette that has the potential to release the contents (such as cutting into the hollow/liquid-containing part of the pipette stem) in the prescribed test time of 5 min. for the 1st pkg or 1 min. for the 2nd pkg, or accessing any amount of placebo/water while opening the blister in the prescribed test time of 5 min. for the 1st pkg or 1 min. for the 2nd pkg.

A **child failure** is access to 1 unit. Access to 1 unit is more than 28.5mg of Fipronil for all sizes.

A **unit failure** is access to the pipette or any partial or complete access to the placebo (water).

Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1028mg/ml x 0.097 Fipronil] = 0.286ml = **0.29ml for Fipronil only products**

Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1022.3mg/ml x 0.098 Fipronil] = .284ml = **0.28ml for Fipronil & S-Methoprene Cat**

Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1020mg/ml x 0.098 Fipronil] = 0.285ml = **0.29ml for Fipronil & S-Methoprene Dog**

% AI - Fipronil 9.8%

S-Methoprene 11.8%

Note:

1. **The blister is the child-resistant feature.**
2. **The pipettes are filled in fl. oz. (5/26/10 telephone call R. Gross/D. Petrick). The pipette sizes in ml are based on [29.6ml per fl. oz. x number of fl. oz. on the pipettes]. The final label must show pipette sizes labeled in fl. oz. The number of ml on label should be based on [29.6ml per fl. oz. x number of fl. oz. on the pipettes].**
3. **16 CRP studies were submitted by the Company to cover the 5 sizes (0.017, 0.023, 0.045, 0.091, and 0.136 fl. oz.) in 2 colors (purple and teal). No studies were submitted for the 0.023 fl. oz. size in either color. No extrapolation was allowed. In the purple color the 0.017 fl. oz. size (MRID 480057-02) 4 child failures were reported by the company, which is a pass of the 50 child test in 16 CFR 1700.20. However, it is a marginal pass as 5 child failures is the maximum for a 50 child pass in 16 CFR 1700.20. Therefore, it will not be used for extrapolation purposes. In the teal color the 0.017 fl. oz. size (MRID 480132-03) a 90% Senior Adult Use Effectiveness (SAUE) was reported by the company, which is a marginal pass of the SAUE per 16 CFR 1700.15(b)(2)(i) per the protocol in 16 CFR 1700.20. Therefore, it will not be used for extrapolation purposes.**

July 22, 2010

CRPdatasummarycht

EPA REG # 86230-U LC-2010-4 Plus Fipronil & S-Methoprene For Dogs

Chemical - Fipronil 9.8%
S-Methoprene 8.8%

Company Name Lorado Chem Inc.

A **Senior Adult Use Effectiveness failure** is failure to access the pipette in the prescribed test time of 5 min. for the 1st pkg or 1 min. for the 2nd pkg, breaking or cutting the pipette that has the potential to release the contents (such as cutting into the hollow/liquid-containing part of the pipette stem) in the prescribed test time of 5 min. for the 1st pkg or 1 min. for the 2nd pkg, or accessing any amount of placebo/water while opening the blister in the prescribed test time of 5 min. for the 1st pkg or 1 min. for the 2nd pkg.

A **child failure** is access to 1 unit. Access to 1 unit is more than 28.5mg of Fipronil for all sizes.

A **unit failure** is access to the pipette or any partial or complete access to the placebo (water).

Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1028mg/ml x 0.097 Fipronil] = 0.286ml = **0.29ml for Fipronil only products**

Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1022.3mg/ml x 0.098 Fipronil] = .284ml = **0.28ml for Fipronil & S-Methoprene Cat**

Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1020mg/ml x 0.098 Fipronil] = 0.285ml = **0.29ml for Fipronil & S-Methoprene Dog**

% AI - Fipronil 9.8%

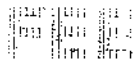
S-Methoprene 8.8%

Note:

1. **The blister is the child-resistant feature.**
2. **The pipettes are filled in fl. oz. (5/26/10 telephone call R. Gross/D. Petrick). The pipette sizes in ml are based on [29.6ml per fl. oz. x number of fl. oz. on the pipettes]. The final label must show pipette sizes labeled in fl. oz. The number of ml on label should be based on [29.6ml per fl. oz. x number of fl. oz. on the pipettes].**
3. **16 CRP studies were submitted by the Company to cover the 5 sizes (0.017, 0.023, 0.045, 0.091, and 0.136 fl. oz.) in 2 colors (purple and teal). No studies were submitted for the 0.023 fl. oz. size in either color. No extrapolation was allowed. In the purple color the 0.017 fl. oz. size (MRID 480057-02) 4 child failures were reported by the company, which is a pass of the 50 child test in 16 CFR 1700.20. However, it is a marginal pass as 5 child failures is the maximum for a 50 child pass in 16 CFR 1700.20. Therefore, it will not be used for extrapolation purposes. In the teal color the 0.017 fl. oz. size (MRID 480132-03) a 90% Senior Adult Use Effectiveness (SAUE) was reported by the company, which is a marginal pass of the SAUE per 16 CFR 1700.15(b)(2)(i) per the protocol in 16 CFR 1700.20. Therefore, it will not be used for extrapolation purposes.**

EPA REG #	MRID	PKG Description include ml per Pkg # unit/pkg, child fail = # units, color, tox/harm = # units	# Pkges Child Get at Begin Test	Company Data		Data		Conclusion include CRE & SAUE via computer analysis
				CRE	SAUE	Comprehens ive Review & why	Only Comp uter Analy sis	
86230-U dog Fipronil & S- Methopren e	480131-03 GLM 29087 senior	teal pipette @ 0.045 fl. oz. (1.33ml) in a blister and three blisters attached to each other as a card. Water placebo in pipette. Tox/harm = 1 pipette, child fail = 1 pipette	1 card with 3 blisters		94% SAUE 6 Fail = 6 Fail open pkg B	X ? SAUE per raw data sheet comments		CRP certification dated 2/25/10 is ok. Label submitted 6/1/2010 page 9 label on CRP has same CRP directions as in study, label on box and pkg insert refer consumer to back of CRP for opening directions. Note this is acceptable. However in the storage section of the label the statement should be changed to read "Store unused application pipettes in the original unopened child-resistant container and...." Review of the comments on the raw data sheets indicated 8 subjects whose results were inconclusive. Additional clarifications consisting of an explanation and photographs(test packages) are necessary to allow the Agency to determine whether or not these packages should be considered successfully opened. Note the comments on the raw data sheets need to be reasonably reconciled with the explanation and photographs of the test packages to allow the Agency to determine whether or not these packages should be considered successfully opened. These 8 subjects are a 54 year old female package 14, a 53 year old male package 20, a 51 year old male package 24, a 59 year old female package 26, a 58 year old female package 43, a 64 year old female package 82, a 68 year old male package 87, and a 61 year old male package 92. Data Analysis demonstrated errors in the electronic version due to inputting package 71 twice. A new electronic version was submitted. Data Analysis of it showed 6 senior failures, (a 51 year old female, two 63 year old females, a 66 year old male, a 66 year old female, and a 69 year old female failed to open package B). In conclusion results are inconclusive. CRP SAUE requirements are not met.
86230-U dog Fipronil & Methopren e	480131-05 GLM 29088 child	teal pipette @ 0.091 fl. oz. (2.69ml) in a blister and three blisters attached to each other as a card. Water placebo in pipette. Tox/harm = 1 pipette, child fail = 1 pipette	1 card with 3 blisters	2 child failure = Pass 50 child test. 2 children each opened 1 blister.			X	CRP certification dated 2/25/10 is ok. Label submitted 6/1/2010 page 9 label on CRP has same CRP directions as in study, label on box and pkg insert refer consumer to back of CRP for opening directions. Note this is acceptable. However in the storage section of the label the statement should be changed to read "Store unused application pipettes in the original unopened child-resistant container and...." Data Analysis showed 2 errors in the electronic data, a 48 month old male had the incorrect birth date entered and a 44 month old female had the incorrect birth date entered. Both subjects ages were correct once their birth dates were located. There were 2 child failures, a 48 month old female, and a 50 month old male each accessed 1 pipette. Study is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.

EPA REG #	MRID	PKG Description Include ml per Pkg # unit/pkg, child fail = # units, color, tox/harm = # units	# Pkges Child Get at Begin Test	Company Data		Data		Conclusion include CRE & SAUE via computer analysis
				CRE	SAUE	Comprehens ive Review & why	Only Comp uter Analy sis	
86230-U dog Fipronil & S- Methopren e	480131-02 GLM 29086	teal pipette @ 0.136 fl. oz. (4.03ml) in a blister and three blisters attached to each other as a card. Water placebo in pipette. Tox/harm = 1 pipette, child fail = 1 pipette	1 card with 3 blisters		95% SAUE 5 Fail = 5 Fail open pkg B	X ? SAUE per raw data sheet comments		CRP certification dated 2/25/10 is ok. Label submitted 6/1/2010 page 9 label on CRP has same CRP directions as in study, label on box and pkg insert refer consumer to back of CRP for opening directions. Note this is acceptable. However in the storage section of the label the statement should be changed to read "Store unused application pipettes in the original unopened child-resistant container and...." Review of the comments on the raw data sheets indicated 4 subjects whose results were inconclusive. Additional clarifications consisting of an explanation and photographs (test packages) are necessary to allow the Agency to determine whether or not these packages should be considered successfully opened. These 4 subjects are a 51 year old female package 27, a 57 year old female package 39, a 63year old female package 62, and a 61 year old male package 95. Data Analysis showed 5 senior failures, (a 55 year old female, two 68 year old females, a 69 year old female, and a 70 year old female failed to open package B). In conclusion results are inconclusive. CRP SAUE requirements are not met.



DP BAR CODE NO.: 376315 FILE SYMBOL NO.: 86230-E DECISION NO.: 429489
PC Code(s): 129121 ACTION CODE: R310
FOOD Use: NO NON-FOOD Use: Yes

DATE OUT: June 29, 2010

SUBJECT: End Use Product Chemistry Review
Product Name: LC-2010-2 Fipronil for Dogs

FROM: Hari Mukhoty, Product Chemistry Team
Technical Review Branch / Registration Division (7505P)

TO: Bonaventure Akinlosotu / Richard Gepken PM - 10
Insecticide Branch / Registration Division (7505P)

Handwritten: JMC. 8/29/10
6/29/10

Company Name: Loradochem, Inc.
Formulation Type: Liquid

INTRODUCTION:

The Registrant re-submitted one basic CSF (dated 06/29/2010) and a proposed product specific label (dated 03/05/2010) for registration of the aforesaid product under EPA File Symbol No. 86230-E.

The applicant claims that the proposed product is substantially similar to another registered product EPA Reg. No. 65331-3 (Product name: Frontline Top Spot).

TRB has been requested to evaluate the product chemistry data required for the registration of the proposed basic product and to determine if the proposed product is substantially similar to the cited product.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Fipronil (9.7%).
2. The source material of the active ingredient is not registered with the Agency and the CSF is undergoing review for registration.
3. All inert ingredients have been screened by IAB on 06/29/2010 and found to be approved for non-food uses only.

DP BAR CODE NO.: 376315 FILE SYMBOL NO.: 86230-E DECISION NO.: 429489
PC Code(s): 129121 ACTION CODE: R310
FOOD Use: NO NON-FOOD Use: Yes

4. Confidential Statement of Formula(s):

☒ Basic - Dated: 03/05/2010 resubmitted (email) – Dated: 06/29/2010

☐ Alternate # - Dated:

Alternate CSF(s) complies with 40CFR§152.43: ☐ Yes ☐ No

5. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concur with product label (PR Notice 91-2)

☒ Yes, if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA;

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

b. Health related sub statements:

Petroleum distillate at > 10%: ☐ Yes ☐ No ☒ NA

Methanol at > 4%: ☐ Yes ☐ No ☒ NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☒ Yes ☐ No

The flash point is 129°F. Product label should contain a statement: Combustible. Do not use or store near heat or open flame. The product is not potentially explosive and not labeled for use around electrical equipment.

Is the sub statement in compliance with PR Notice 97-6? ☒ No - Uses the term "Inert ingredients"

, if not, explain below: Recommended term is "Other ingredients"

d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No – from product chemistry point of view; if yes explain below:

Final decision of overall label acceptance will be made by the PM.

DP BAR CODE NO.: 376315 FILE SYMBOL NO.: 86230-E DECISION NO.: 429489
 PC Code(s): 129121 ACTION CODE: R310
 FOOD Use: NO NON-FOOD Use: Yes

6. Group A: Product Chemistry Data

TRB's determination of the acceptability of the data for the proposed product is listed in the tables below.

Guideline No.	Study Title	Data submitted		TRB's Assessment of Data	MRID Nos.
		Yes	No		
830.1550	Product Identity & Composition	X		A	480130-01
830.1600	Description of materials used to produce the product	X		A	"
830.1650	Description of formulation process	X		A	"
830.1670	Discussion on the formation of impurities	X		A	"
830.1700	Preliminary analysis	N/A			
830.1750	Certified limits (158.350)	Standard certified Limits	X	A	
		Proposed Limits			
		Justification for wider limits			
830.1800	Enforcement analytical method	X	I	A	"

A = Acceptance, N = Not Acceptable, G = Data Gap,
 W = Waiver Request, I = In Progress, NA = Not Applicable

DP BAR CODE NO.: 376315 FILE SYMBOL NO.: 86230-E DECISION NO.: 429489
PC Code(s): 129121 ACTION CODE: R310
FOOD Use: NO NON-FOOD Use: Yes

7. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos. 480130-01
830.6303	Physical State	Liquid	A	"
830.6315	Flammability	Flash point \geq 129°F	A	"
830.6316	Explosibility	N/A	A	"
830.7000	pH	G	N	"
830.7300	Density (units)	1.028 g/ml (Sp. Gravity)	A	"

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request,
NA = Not applicable, I = In progress

CONCLUSIONS:

1. TRB has reviewed the CSF for the proposed basic product and has found it to be acceptable pending the acceptance of the CSF of the source of the active ingredient which is currently undergoing review. The CSF of the proposed basic is attached with this review. The proposed basic product is substantially similar to the cited product from product chemistry point of view.
2. Product chemistry data requirements for Group A and Group B, with the exception of pH (830.7000), and one year storage stability (830.6317) and corrosion characteristics (830.6320) data are satisfied and acceptable.
3. The registrant must generate one year storage stability (830.6317) and corrosion characteristics (830.6320) data on the proposed product. It is required that the observations be made at 0, 3, 6, 9, and 12 month intervals. The results must be submitted to the Agency in electronic and hard copy format.
4. The proposed label was screened as it pertains to the product chemistry requirements. The final review of the proposed label and uses are the purview of the PM team.

LoradoChem, Inc.

OK Cert
PLG 5/28/10

CHILD RESISTANT PACKAGING CERTIFICATION

COMPANY: LoradoChem, Inc., Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, PA 19104-2891

PRODUCT: LC-2010-2 Fipronil for Dogs EPA File Symbol: 86230-E

"I certify that the packaging that is being used for this product will meet the standards of 40 CFR 157.32."

Date : February 25, 2010



John Caldwell
Assistant Secretary, LoradoChem Inc.



United States Environmental Protection Agency
OPP – RD – IB
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

February 25, 2010

Attention: Richard Gebken

Dear Mr. Gebken

LETTER OF AUTHORIZATION

Velcera, Inc. FidoPharm hereby authorizes the U.S. Environmental Protection Agency to accept the submission of, and use of the following studies in support of the registrations of the LoradoChem Inc.'s products containing fipronil + S-methoprene.

Child Resistant Packaging Tests (Child panels and Senior panels)

Laboratory: Great Lakes Marketing
3013 Executive Parkway
Ste 106
Toledo OH 43606

Child Panels

Study Number	Product
29089	LC-2010-1 & LC-2010-2
29090	LC-2010-2
29092	LC-2010-2
10050	LC-2010-2
29082	LC-2010-3 & LC-2010-4
29087	LC-2010-4
29088	LC-2010-4
29083	LC-2010-4

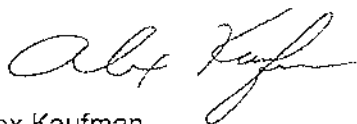
Seniors Panels

Study Number	Product
10052	LC-2010-1 & LC-2010-2
10053	LC-2010-2
10057	LC-2010-2
10058	LC-2010-2
28081	LC-2010-3 & LC-2010-4
29087	LC-2010-4
29088	LC-2010-4
29086	LC-2010-4

Velcera, Inc.

Should you have any questions or require further information please contact Dr. Iain Weatherston of Technology Sciences Group, Inc. at 623-535-4060 or jazkatz@questoffice.net

Sincerely,

A handwritten signature in black ink, appearing to read "Alex Kaufman". The signature is fluid and cursive, with the first name "Alex" and last name "Kaufman" clearly distinguishable.

Alex Kaufman
President & CEO
FidoPharm

Product Performance Data Evaluation Report
By Kevin J. Sweeney, Senior Entomologist, Insecticides Branch

Kevin J. Sweeney
9/22/10

Date: September 22, 2010

Reviewer: Bonaventure Akinlosotu

Product: LC-2010-2 Plus Fipronil for Dogs

EPA Registration No.: 86230-2 (E)

PM: Richard Gebken, PM 10

Action: R310

Decision: 429489

DP No: 376317

OPPTS Guideline: 810.3300

Insecticides: 9.7% fipronil (PC code 129121)

App rate: apply in accordance with dog weight class ranges listed on label.

Formulation: RTU spot-on

GLP studies: studies were cited from a similar product - EPA Reg. No. 65331-3

Pests: fleas, ticks, sarcoptic mange (scabies) mite, chewing lice

Use pattern/application rate: Spot-on to dog. Apply to one-spot between shoulders.

Label review and data citation.

The label with its claims, use pattern, and pests is almost exactly the same as the cited product. Provided the subject product chemistry is found to be substantially similar to the cited product, the cited efficacy data will support the product performance data requirement.

Entomologist's Recommendation:

1. The cited product and "cite-all" method to fulfill the product performance data requirement are acceptable.
2. If applicable, a table of weight ranges and doses should be on the Master Label. The weight ranges and doses should be the same as on the cited-product. If not, the cited product performance data may not support the product performance data requirement.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 27, 2010

MEMORANDUM

Subject: Name of Pesticide Product: LC-2010-2 FIPRONIL FOR DOGS
EPA Reg. No. /File Symbol: 86230-E
DP Barcode: DP 376316
Decision No.: 429489
Action Code: R310
PC Codes: 129121 (Fipronil: 9.7%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
07-27-2010

M. Haslam

To: Bonaventure Akinlosotu/Richard Gebken, RM 10
Insecticide Branch
Registration Division (7505P)

Registrant: LORADO CHEM, INC.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129121 Fipronil	9.7%
<u>Inert Ingredient(s):</u>	90.3%
TOTAL	100.0%

ACTION REQUESTED: The Risk Manager requests:

"For your review... New EP registration, presumably me-too of 65331-3... Tech source [REDACTED]
[REDACTED] not registered; pending review..."

Product ingredient source information may be entitled to confidential treatment

BACKGROUND:

As originally received, the material included a copy of a letter (dated March 4, 2010, stating on p. 6 that this product is identical/substantially similar to 65331-2, corrected to 65331-3) from the registrant, a CSF for the proposed product, a data matrix (indicating on page 3 “cite-all” for the acute toxicity studies and companion animal safety studies) and a proposed label, stating that the product “comes in 4 different treatments [dosage amounts?] for different-sized dogs and puppies eight (8) weeks or older.” The four dog size weight ranges are listed as: 1) Up to 22 lbs; 2) 23 to 44 lbs; 3) 45 to 88 lbs; and 4) 89 to 132 lbs. From information on p. 9 of the label “Dog 88 – 0.091 fl oz” [perhaps a typo for Dogs 44-88 lbs – 0.091 fl. oz.] and from p. 10 the 0.045 fl. oz size would be for dogs 23-44 lbs, with no further information as to the amount of product that would be appropriate for the other sizes. The dosage rates of the cited product (Frontline Top Spot for Dogs, EPA Reg. No. 65331-3) are the following: Up to 22 lbs: 0.023 fl. oz. or 0.67 mL; 23-44 lbs: 0.045 fl. oz. or 1.34 mL; 45-88 lbs: 0.091 fl. oz. or 2.68 mL; 89-132 lbs: 0.136 fl. oz. or 4.02 mL. The contents of an applicator would be applied to a single spot behind the neck and between the shoulders. The label specifies use (application to) adult dogs and puppies 8 weeks of age or older, and states that it is not to be reapplied for 30 days.

A revised label for this product was e-mailed to this reviewer by Iain Weatherston on July 27, 2010, along with additional information indicating the following dosage rates for this product (and for 86230-U):

Dog Up to 22 lbs: 0.023 fl.oz. (0.067 mL)

Dog 23-44 lbs: 0.045 fl.oz. (1.34 mL)

Dog 45-88 lbs: 0.091 fl.oz. (2.68 mL)

Dog 89-132 lbs: 0.136 fl. oz. (4.02 mL)

These dosage rates are the same as those for EPA Reg. No. 65331-3:

COMMENTS AND RECOMMENDATIONS:

1. After a comparison of the CSF for 86230-E and that of EPA Reg. No. 65331-3, TRB concludes that, although there some differences involving inert ingredients, the two formulations are substantially similar with respect to acute toxicity and companion animal safety considerations. In addition, the use(s) and exposures are probably identical (both labels specify application to a single spot behind the neck and between the shoulders of adult dogs and puppies 8 weeks of age and older, and the minimum period specified between applications – 30 days – is the same for both products). **TRB concludes that the registration of EPA File Symbol 86230-E can be supported toxicologically as a “me-too” on the basis of substantial similarity to EPA Reg. No. 65331-3.**

2. [REDACTED] (the technical source of fipronil for 86230-E) should be registered before 86230-E is registered.

3. The proposed label for 86230-E includes the following (Sublabel B: Package Insert): “Fipronil, when applied as directed, will accumulate in hair follicles and skin oil to then be released onto the coat and skin, allowing for lasting control.” A similar statement (“Fipronil

collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity.”) appears on the last accepted (March 9, 2010) label for 65331-3. TRB recommends that these statements be deleted from their respective labels.

4. EPA Reg. No. 65331-3 was one of the products evaluated by the Agency in its review of enhanced reporting of pet spot-on incidents for 2008. As a result of this evaluation and current discussions with the registrant, there will be labeling revisions for 65331-3. TRB recommends, as a condition for registration, that the same labeling revisions be applied to 86230-E when they go into effect for 65331-3.

5. The registrant should be made aware that the Agency is considering, on a case-by-case basis, making pet spot-on registrations (new and existing products when approving amendments) time-limited to expire two years after the product is released for shipment. This could allow for post-market surveillance of the incidents for these products before the guidelines are revised to include pre-market clinical trials.

6. The CSF for 86230-E should also be reviewed and accepted by the TRB chemistry team.

Master Label containing:

Sublabel A: Box Label

Sublabel B: Package Insert

Sublabel C: Labeling on the Child Resistant Package

Sublabel D: Labeling on the Pipette

Sublabel E: Stickers for Re-application Reminders

LC-2010-2 FIPRONIL FOR DOGS

ACTIVE INGREDIENT

Fipronil.....9.7%
INERT INGREDIENTS.....90.3%
TOTAL.....100.0%

(Picture of dog)

KEEP OUT OF REACH OF CHILDREN

CAUTION

Contains X-0.0XX fl.oz (X.xx mL) applicator pipette(s)

EPA Reg. No. 86230-E

EPA Est. No. XXXXX-XXX-XXX

Sublabel A: Box Label

[Front Panel of Box]

LC-2010-2 FIPRONIL FOR DOGS

Picture of Applicator Pipettes
1, 3, or 6

Kills fleas, ticks, and chewing lice

- Fast action
- Kills ticks, including potential Lyme disease-carrying ticks
- Waterproof
- Lasting control

Used on Dogs XX to XX lbs.

ACTIVE INGREDIENT

Fipronil.....9.7%
INERT INGREDIENTS.....90.3%
TOTAL.....100.0%

(Picture of dog)

KEEP OUT OF REACH OF CHILDREN

CAUTION

Contains X-0.0XX fl.oz (X.xx mL) applicator pipette(s)

Compare to Frontline® Top Spot same active ingredient*
#1 Veterinarian Recommended active ingredient

[Back Panel of Box]

LC-2010-2 FIPRONIL FOR DOGS

LC-2010-2 FIPRONIL FOR DOGS acts fast and is an effective, lasting, waterproof, and easy-to-use treatment for control of fleas, ticks, and chewing lice on dogs and puppies weighing XX-XX lbs.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply this product. READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Apply LC-2010-2 FIPRONIL FOR DOGS to dogs and puppies aged 8 weeks or older, including on breeding, pregnant, and lactating bitches, as indicated below for control of fleas, ticks (including all stages of American Dog ticks, Brown Dog ticks, Deer ticks and Lone Star ticks), and chewing lice:

Picture of Applicator Pipette

- Open the child-resistant package and remove an applicator pipette. Use scissors and cut across the top as shown, then peel the foil down and lift out the applicator pipette.
- While keeping the applicator pipette upright and away from your face and body, snap the tip of the applicator pipette away from you as shown.
- Part the dog's hair and place the tip of the applicator pipette to the skin level behind the neck and between the shoulders and ensure that the entire application of LC-2010-2 FIPRONIL FOR DOGS is contained to a single spot on the dog's skin. Be sure to squeeze the applicator pipette thoroughly so that the entire contents are applied.
- Try to keep the product from being applied superficially on the dog's hair. Use only one applicator pipette during each treatment.
- Do not touch the area where the application was made until it is dry.

LC-2010-2 FIPRONIL FOR DOGS may also assist in controlling sarcoptic mange infestations through multiple applications each month.

Frequency of Application

Fleas: According to research studies, adult fleas are killed for up to three months following an application of fipronil. If, however, your dog or puppy is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, it is recommend to reapply once every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply LC-2010-2 FIPRONIL FOR DOGS for thirty (30) days.

*This product is not manufactured or distributed by Merial, the makers of Frontline®

Name of Registrant
Address of registrant

©2010 registrant. All rights reserved.

EPA Reg. No. 86230-E
EPA Est No.

Please call 1-800-XXX-XXXX if you have any questions about LC-2010-2 FIPRONIL FOR DOGS.

Same active ingredient as Frontline®

Ingredient	LC-2010-2 Fipronil for Dogs	Frontline®
Fipronil	9.7%	9.7%
Inert Ingredients	90.3%	90.3%
TOTAL	100%	100%

[Top Panel of Box]

LC-2010-2 for dogs

For dogs XX-XX lbs.

X applicator pipette(s)

[Bottom Panel of Box]

For animal use only

[Right side panel of Box]

LC-2010-2 FIPRONIL FOR DOGS

For dogs XX-XX lbs.
X applicator pipette(s)

[Left side panel of Box]

Lot Number:

X applicator pipette(s)

Sublabel B: Package Insert

LC-2010-2 FIPRONIL FOR DOGS for Dogs and Puppies

For use on dogs and puppies 8 weeks or older

LC-2010-2 FIPRONIL FOR DOGS is a topical treatment for fast action and lasting control of fleas, ticks, and chewing lice.

ACTIVE INGREDIENT

Fipronil.....	9.7%
INERT INGREDIENTS.....	90.3%
TOTAL.....	100.0%

Compare to Frontline® Top Spot same active ingredient*

KEEP OUT OF REACH OF CHILDREN

CAUTION

LC-2010-2 FIPRONIL FOR DOGS acts fast and is an effective, lasting, waterproof, and easy-to-use treatment for control of fleas, ticks, and chewing lice on dogs and puppies. When used as directed, LC-2010-2 FIPRONIL FOR DOGS can stop infestations of fleas, ticks, and chewing lice and help to prevent re-infestation on dogs and puppies, including on breeding, pregnant and lactating bitches. LC-2010-2 FIPRONIL FOR DOGS can also assist in controlling sarcoptic mange infestations.

Specifically, LC-2010-2 FIPRONIL FOR DOGS kills, controls and prevents infestations of:

- 1) newly emerged adult fleas prior to egg-laying, including fleas which could cause flea allergy dermatitis;
- 2) Brown Dog tick, the American Dog tick, the Lone Star tick, and the Deer tick (potential Lyme disease-carrier), at all stages; and
- 3) chewing lice infestations.

LC-2010-2 FIPRONIL FOR DOGS contains the active ingredient fipronil. Fipronil, when applied as directed, will accumulate in hair follicles and skin oil to then be released onto the coat and skin, allowing for lasting control.

Directions For Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply this product. **READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL**

PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Apply LC-2010-2 FIPRONIL FOR DOGS to dogs and puppies aged 8 weeks or older, including on breeding, pregnant, and lactating bitches, as indicated below for control of fleas, ticks, and chewing lice:

Pictures to be provided

- Open the child-resistant package and remove an applicator pipette. Use scissors and cut across the top as shown, then peel the foil down and lift out the applicator pipette.
- While keeping the applicator pipette upright and away from your face and body, snap the tip of the applicator pipette away from you as shown.
- Part the dog's hair and place the tip of the applicator pipette to the skin level behind the neck and between the shoulders and ensure that the entire application of LC-2010-2 FIPRONIL FOR DOGS is contained to a single spot on the dog's skin. Be sure to squeeze the applicator pipette thoroughly so that the entire contents are applied.
- Try to keep the product from being applied superficially on the dog's hair. Use only one applicator pipette during each treatment.
- Do not touch the area where the application was made until it is dry.

LC-2010-2 FIPRONIL FOR DOGS may also assist in controlling sarcoptic mange infestations through multiple applications each month.

Frequency of Application

Fleas: According to research studies, adult fleas are killed for up to three months following an application of fipronil. If, however, your dog or puppy is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, it is recommend to reapply once every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply LC-2010-2 FIPRONIL FOR DOGS for thirty (30) days.

Please note that there is no need to reapply following your dog's exposure to sunlight, bathing or water immersion, as Fipronil remains effective in those conditions.

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

Storage. Store unused application pipettes in the original child-resistant container and outer box only, out of reach of children and animals.

Pesticide Disposal. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Container Disposal. Nonrefillable container. **If empty:** Do not reuse this container. Place in trash or offer for recycling if available.

First Aid

Have the product container or label with you when calling a poison control center or doctor, or if going for treatment.

If Swallowed: Immediately call a poison control center or doctor for treatment advice. Have the person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

If on Skin: Rinse skin with plenty of soap and water. Get medical attention if irritation persists.

PRECAUTIONARY STATEMENTS

Hazards to Humans. Caution.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Hazards to Domestic Animals.

For external use only. Do not use on puppies under 8 weeks of age. Sensitivities may occur after using ANY pesticide product for pets. While temporary irritation at the application area may occur, if signs of continued sensitivity occur, consult a veterinarian immediately. Should any unusual reactions to the application occur, do not reapply before consulting with a veterinarian. Certain medications can interact with pesticides. Consult with your veterinarian before using this product on medicated, debilitated, or aged dogs. Call 1-800-XXX-XXXX for 24-hour assistance.

Physical or Chemical Hazards

Flammable: Keep away from heat and open flame.

Treatment Options for Different Sizes of Dogs

LC-2010-2 comes in four different treatments for different-sized dogs and puppies eight (8) weeks or older:

* Up to 22lbs.

- * 23 to 44 lbs.
- * 45 to 88 lbs.
- * 89 to 132 lbs.

Same active ingredient as Frontline®

Ingredient	LC-2010-2 FIPRONIL FOR DOGS	Frontline®
Fipronil	9.7%	9.7%
Inert Ingredients	90.3%	90.3%
TOTAL	100%	100%

Warranty

Seller makes no warranty, express or implied, concerning the use of this product other than as indicated on the labeling. Buyer assumes all risk of use and handling of the product when such use and handling are contrary to the label instructions.

* This product is not manufactured or distributed by Merial, the makers of Frontline Top Spot

EPA Reg. No. 86230-E
EPA Est.

Registrant name and address

©2010 registrant. All rights reserved.

Sublabel C: Labeling on the Child Resistant Package

Top of lidding foil: Dotted line with representation of a scissors

Company Name: LoradoChem

Product Name: LC-2010-2 FIPRONIL FOR DOGS

Graphic picture of the pipette

Instructions: **To Open Package:**
 Use scissors to cut
 across the top as shown.
 Peel down the foil
 completely before
 removing pipette.

Species and amount (example): Dog 88 – 0.091 fl oz

Lot number: Lot No:

Sublabel D: Labeling on the Pipette

Neck of pipette: Contains: fipronil (9.7%)

Body of pipette: **LoradoChem**
Example: 0.045 fl.oz.
LC-2010-2 FIPRONIL FOR DOGS

For Dogs 23-44 lbs.
Keep out of reach of children
See full label for
additional directions
Caution
EPA Reg. No. 86230-E

Sublabel E: Stickers for Re-application Reminders

LC-2010-2 FIPRONIL FOR DOGS

Flea, Tick, and Chewing Lice
Care Card

Picture of Dog

Month 1

Picture of pipette

Date of Treatment

Month 2

Picture of pipette

Date of Treatment

Month 3

Picture of pipette

Date of Treatment

Place sticker on your calendar or refrigerator to remind you to administer LC-2010-2 FIPRONIL FOR DOGS to your dog



Re: LoradoChem Registration Application 86230-R-E-G-U

IAIN WEATHERSTON to: Marion Johnson

03/31/2010 12:50 AM

Cc: Bonaventure Akinlosotu, Richard Gebken, "Robert Stewart", Lois Rossi, Linda Arrington, George Herndon

Dear Marion:

Now it is my turn to apologize for not responding to your e-mail yesterday. I thank you for the e-mail, the rescinding of the decision to issue a 75-day deficiency letter for each application and for your work towards to resolving the issue of setting the PRIA approval date. I look forward to working with you, Richard and Bonaventure to decide on a date which meets both the Agency's review scheduling and evaluation process yet meets the expectations of my client.

Although as of yet no PRIA approval date has been suggested or shared with me (and I understand that the issues have so far precluded this) I believe that the approval dates for the four LoradoChem products should fall within the span of September 26 - 30, 2010. I am working with [REDACTED] and have been told by them, confirmed by Richard, that the PRIA approval date for their technical registration is [REDACTED]. I would believe that sometime before this date the Agency would be in a position to determine that the [REDACTED] material is "registerable."

I appreciate that the product chemistry review of the LoradoChem applications depends on the [REDACTED] product chemistry package but I believe that there is no impediment at this time to a review of all of the CRP testing done by my client since the pipettes in the packaging do not contain product and the integrity of the packaging and a successful CRP test is not in any way dependent on the [REDACTED] application.

I also appreciate and thank you for your willingness to work with Richard and the reviewers to minimize any delay which may arise from factors in the review of the [REDACTED] technical material. Be assured that I will work with Agency personnel diligently to supply any information or requested material in a most expeditious manner so as to avoid any delays.

Best regards,
Iain

Iain Weatherston
Senior Managing Consultant
Technology Sciences Group
623-535-4060 T
jatzkatz@qwestoffice.net

----- Original Message -----

From: <Johnson.Marion@epamail.epa.gov>
To: "IAIN WEATHERSTON" <jatzkatz@qwestoffice.net>
Cc: <Akinlosotu.Bonaventure@epamail.epa.gov>;
<Gebken.Richard@epamail.epa.gov>; "Robert Stewart" <RStewart@TSGUSA.COM>;
<Rossi.Loïs@epamail.epa.gov>; <Arrington.Linda@epamail.epa.gov>; "Jeff Herndon" <herndon.george@epa.gov>
Sent: Monday, March 29, 2010 12:11 PM
Subject: Re: LoradoChem Registration Application 86230-R-E-G-U

> Iain,

>

> Firstly, I would like to apologize for just getting back to you,

Product ingredient source information may be entitled to confidential treatment

> but I've been working to reach some resolution to the issue, which I've
> already discussed with Bonaventure and Richard. Having received your
> memorandum of March 24, 2010 opposing the Insecticide Branch's verbal
> decision to not allow the subject applications to proceed, since the
> source products of the active ingredient are pending with the agency, I
> consulted with Ms. Arrington about the specifics of your mutual
> discussions on the revision of the original PRIA codes for the
> applications. While the PRIA codes have now been modified to that of a
> "310", and the resulting additional fees have been paid, we are now only
> faced with the immediate issue of the source product, which is pending
> registration with the agency.

> You are correct in your assertion that the agency has allowed, and
> still allows, the receipt of applications for pesticide registration
> where a source product (i.e., the source of the active ingredient) is
> still pending registration. As a result, there will be no 75 day
> deficiency letter sent to you or your client citing that your
> application is deficient based upon the lack of a "registered source
> product". However, since the agency cannot fully evaluate the product
> chemistry data until which time a regulatory determination can be made
> on the pending source product, the agency may need to extend the
> application time period for the subject applications to allow the
> appropriate amount of time to review the submitted data, once the source
> product has been registered, or an alternative regulatory determination
> is made. I will work with the Product Manager and reviewer to ensure
> that the additional time needed is discussed with you, so as to have as
> timely decision completed as possible.

> Please let me know if you have further questions, or let me know
> if you need additional clarification. Otherwise, I will look forward to
> this issue proceeding smoothly.

>
>
> regards,

Best

>
>
>
> Marion J.

> _____
> Marion J. Johnson, Jr.,
> Chief, Insecticide Branch
> U.S. Environmental Protection Agency
> Office of Pesticide Programs
> Registration Division
> (703) 305-6788 (tel.)
> (703) 308-0029 (fax)
> johnson.marion@epa.gov
> visit: <http://www.epa.gov/pesticides>

> From: "IAIN WEATHERSTON" <jazkatz@qwestoffice.net>

> To: Richard Gebken/DC/USEPA/US@EPA, Marion
> Johnson/DC/USEPA/US@EPA

> Cc: Bonaventure Akinlosotu/DC/USEPA/US@EPA, "Robert Stewart"
> <RStewart@TSGUSA.COM>

> Date: 03/25/2010 01:22 PM

>
> Subject: LoradoChem Registration Application 86230-R-E-G-U
>
>
>
>
>
>
> Richard and Marion:
> I just spoke with BA who tells me that the 1.30 pm teleconference
> cannot go forward because of conflicts you have.
> He suggested that initially I have a conversation with both of you to
> discuss options on how we might progress these registrations. For this
> teleconference there will just be the three of us since I decided not to
> have my colleague Bob Stewart or the [REDACTED] regulatory director
> participate.
> Tomorrow (Friday March 26) I could be available any time between 10 am -
> noon your time (7 am to 9 am Arizona time) but unfortunately the rest of
> my day is already filled. On Monday March 29 I am available from noon
> onwards (east coast time, 9 am onwards Arizona time) and on Tuesday
> March 30 I am available from 10 am (east coast) onwards.
> If you wish me reserve a bridge line (like I did for today) let me know
> and I will supply you with the number, conference line and the password.
> Please let me know what will work for you.
> Regards,
> Iain
>
>
>

Product ingredient source information may be entitled to confidential treatment



Re: Deficient Applications/Submissions: 86230 -R, E, G & U
IAIN WEATHERSTON to: Bonaventure Akinlosotu
Cc: "Robert Stewart", Mark Suarez, Marion Johnson, Richard Gebken

03/25/2010 11:31 AM

Dear Baa:

Looking forward to being able to resolve the fipronil end-use product issues this afternoon.

The call -in number is 202-828-8971

You will be asked for a conference number it is 2

You will be asked for a Pass code, it is [REDACTED]

We should all be in conference in 2 hours

Iain

----- Original Message -----

From: <Akinlosotu.Bonaventure@epamail.epa.gov>

To: "IAIN WEATHERSTON" <jazkatz@qwestoffice.net>

Cc: <Gebken.Richard@epamail.epa.gov>; <Johnson.Marion@epamail.epa.gov>; <Suarez.Mark@epamail.epa.gov>

Sent: Thursday, March 25, 2010 8:11 AM

Subject: Re: Deficient Applications/Submissions: 86230 -R, E, G & U

> Per my conversation with you earlier, Marion, Richard and I will be able
> to talk with you from 1:30 - 2:00 p.m this afternoon. Please confirm and
> provide a phone number for the conf.

> Thanks, baa

> 703-605-0653

>

>

>

>

> From: "IAIN WEATHERSTON" <jazkatz@qwestoffice.net>

>

> To: Bonaventure Akinlosotu/DC/USEPA/US@EPA

>

> Cc: "Robert Stewart" <RStewart@TSGUSA.COM>, "Heather Bjornson" <HBjornson@TSGUSA.COM>

>

> Date: 03/24/2010 05:22 PM

>

> Subject: Re: Deficient Applications/Submissions: 86230 -R, E, G & U

>

>

>

>

>

>

> Dear Dr. Akinlosotu:

> I am sorry about the telephone mail box being full, this is a defect
> with

> the telephone system, it is in fact not full, there are currently no
> messages. I think I will put in a new system within the next three
> weeks. In

> the meantime if you cannot reach me at 623-535-4060, please call

> [REDACTED] which is my home - the two phones are separated by about 20

>

> feet and if I do not answer you will be able to leave a message. Now to
> your

> deficiency e-mail, I did have a call from Richard Gebken on March 22,

> 2010

Commercial/financial information may be entitled to confidential treatment

Personal privacy information

> to explain how he viewed the situation however TSG, LoradoChem (the
> client)
> and [REDACTED] (the manufacturer of the active ingredient) all do not
> agree
> with his opinion and so a letter has already been written to Marion
> Johnson
> as Branch Chief and if the Gebken opinion is not reversed the three
> parties
> TSG, LoradoChem and [REDACTED] will seek a meeting with Lois Rossi in
> order
> to get the four end-use product registrations back on track for a PRIA
> approval date towards the end of September 2010.
> In your e-mail you indicated that you wished to discuss options which
> would
> be available, we would certainly be open to any option which would
> result in
> the current PRIA category and concomitant approval date late in
> September
> 2010 being maintained.
> Since we have already questioned Richard's opinion on the use of a
> Formulator's Exemption strategy in our memorandum to Marion Johnson and
> so
> that we don't get too many parties involved perhaps you could have your
> options included in the Branch Chief's response or available for
> discussion
> if there has to be a meeting or teleconference with Ms. Rossi.
> Best regards,
> Iain
>
> Iain Weatherston, Ph.D.
> Technology Sciences Group Inc.
> 4061 North 156th Drive,
> Goodyear, AZ 85395
> 623-535-4060 T
> jazkatz@qwestoffice.net.
>
>
>
> ----- Original Message -----
> From: <Akinlosotu.Bonaventure@epamail.epa.gov>
> To: <jazkatz@qwestoffice.net>
> Cc: <Gebken.Richard@epamail.epa.gov>; <Suarez.Mark@epamail.epa.gov>
> Sent: Wednesday, March 24, 2010 12:33 PM
> Subject: Deficient Applications/Submissions: 86230 -R, E, G & U
>
>
>>
>> Dr. Weatherston:
>> I have attempted to contact you relative to the subject applications,
>> with no avail. Your voice mail box was full, thus, unable to leave
>> any
>> messages. Initial cursory review of your applications revealed that
>> the
>> stated technical source for the proposed products is not registered.
>> Consequently, the Agency is unable to proceed with the processing of
>> the
>> subject applications. Please give me a call to discuss options, and
>> to
>> advise accordingly.
>> Thanks.
>>
>> _____

>> Bonaventure Akinlosotu, PhD
>> EPS - Regulatory Scientist
>> U.S. Environmental Protection Agency
>> Office of Prevention, Pesticides & Toxic Substances
>> MC 7505P
>> 1200 Pennsylvania Avenue, NW
>> Washington, DC 20460
>>
>> Physical Address
>> One Potomac Yard
>> 2777 Crystal Dr.
>> Arlington, VA 22202
>>
>> 703-605-0653
>> akinlosotu.bonaventure@epa.gov
>>
>> This email may contain material that is confidential, privileged, and/
>> or work product for the sole use of the intended recipient. Any
> review,
>> reliance, distribution by others, or forwarding without express
>> permission is strictly prohibited. If you are not the intended
>> recipient please contact the sender and delete all copies.
>>
>>
>
>
>
>
>
>



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 17, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

TECHNOLOGY SCIENCES GROUP, INC.
LORADOCHEM, INC.
CIRCA CENTRE, 12TH FLOOR
4061 NORTH 156TH DRIVE
GOODYEAR, AZ 85338-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 05-MAR-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



Fw: Your submission to EPA (Reg. no. 86230-U, E)
Fiker Getachew to: jazkatz
Bcc: Sree Nair

03/17/2010 11:22 AM

Mr. Weatherston,

I am sorry my email didn't go through yesterday. I sent it again today morning, i hope you have received it. I just wanted to mention that i will only have the studies till Friday and i will need to pass it out to the PM after that. Could you please have the person you mentioned yesterday send the corrections to me by Friday? Thank You.

Fiker Getachew
EPA Contractor
703-305-6472

----- Forwarded by Fiker Getachew/DC/USEPA/US on 03/17/2010 11:17 AM -----

From: Fiker Getachew/DC/USEPA/US
To: jazkatz@qwestoffice.net
Date: 03/17/2010 09:16 AM
Subject: Your submission to EPA (Reg. no. 86230-U, E)

Mr. Weatherston,

I am sending this email as a follow up to our phone conversation. I am contacting you in reference to your application package for LC-2010-4 Plus Fipronil and S-Methoprene for Dogs and LC02010-2 Fipronil for Dogs (Reg. No. 86230-U, E). Upon review of the application packages and studies, we found quite a few deficiencies. They are listed below:

Reg. No. 86230-U (LC-2010-4 Plus Fipronil and S-Methoprene for Dog

***ALL of the studies i mention below have a confidentiality marking on the pages listed below that contradicts with your No Confidentiality Claim Statement.**

***Studies 2: Page 36**

***Study 3: Pages 30 & 31**

***Study 4: Pages 33 & 34**

***Studies 5: Pages 18 & 19**

***Study 6: Pages 19 & 20**

***Study 7: Page 24**

Also, Formulator's Exemption Statement Form is missing the Pending EPA Reg. No. for Fipronil. It is just says "Pending as EPA Reg. No.". Please send me a revised form with the Reg. no. listed.

Reg. No. 86230-E (LC-2010-2 Fipronil for Dogs)

***The Study i mention below has a page that is illegible due to the poor quality of photocopying.**

***Study 01: Page 6**

The corrections can be faxed to 703-305-5060/Attn: Fiker Getachew or emailed to me.

Thank You

Fiker Getachew
EPA Contractor
703-305-6472

Lorado Chem Corrections
Heather Bjornson
to:
Fiker Getachew
03/17/2010 11:47 AM
Cc:
"IAIN WEATHERSTON"
Show Details

Dear Fiker –

Per Iain Weatherston's request, I am attaching the replacement pages per your e-mail this morning regarding EPA File Symbols 86230-E and 86230-U.

Please do not hesitate to contact me with any questions.

Regards,
Heather R. Bjornson
Technology Sciences Group, Inc.
1150 18th Street NW., Ste. 1000
Washington DC 20036
Tel.: 202-828-8945
Fax: 202-872-0745



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 9, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-429489
EPA File Symbol or Registration Number: 86230-E
Product Name: LC-2010-2 FIPRONIL FOR DOGS
EPA Receipt Date: 05-Mar-2010
EPA Company Number: 86230
Company Name: LORADOCHEM, INC.

IAIN WEATHERSTON
TECHNOLOGY SCIENCES GROUP, INC.
LORADOCHEM, INC.
CIRCA CENTRE, 12TH FLOOR
4061 NORTH 156TH DRIVE
GOODYEAR, AZ 85338-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

The fee associated with this action is \$ 4,578. Payment in the amount of \$ 1,365 has been received. Please remit additional payment in the amount of \$ 3,213

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 979074

St. Louis, MO 63197-9000
By Courier:
U.S. Bank
Government Lockbox 979074
1005 Convention Plaza
SL-MO-C2-GL
St. Louis, MO 63197
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

You may be eligible for a partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

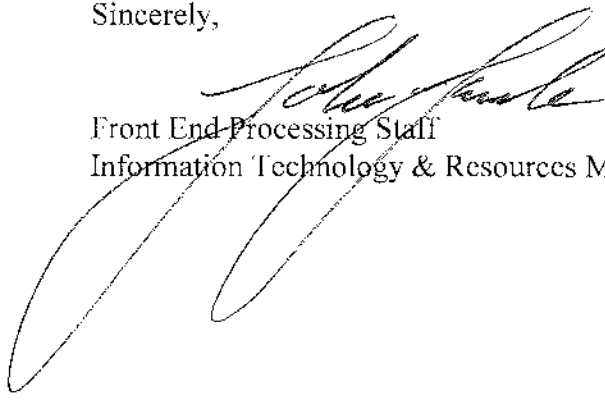
By USPS:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

By Courier:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room S4900 Potomac Yard 1
2777 S. Crystal Dr.
Arlington, VA 22202

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 30 days, the Agency will presume that you no longer want to pursue this action. The Agency will then initiate a process that may result in administrative withdrawal of this action.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 305-6249.

Sincerely,



Front End Processing Staff
Information Technology & Resources Management Division

Heather Bjornson

From: paygovadmin@mail.doc.twai.gov
Sent: Thursday, March 04, 2010 11:40 AM
To: Heather Bjornson
Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Transaction Summary

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 250FQDJ6
Agency Tracking ID: 74104780391

Account Holder Name: Heather R Bjornson
Transaction Type: Sale
Transaction Amount: \$1,365.00
Billing Address: 1150 18th Street, NW
Billing Address 2: Ste. 1000
City: Washington
State/Province: DC
Zip/Postal Code: 20036
Country: USA
Card Type: American Express
Card Number: *****1436
Transaction Date: Mar 4, 2010 11:39:54 AM

Decision Number:
Registration Number: 86230-E
Company Name: LoradoChem, Inc.
Company Number: 86230
Action Code: R300

Richard Gebken
Insecticide Branch
Registration Division
Office of Pesticide Programs
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

March 4, 2010

SUBJECT: Application to register LC-2010-2 Fipronil for Dogs, an insecticide to control fleas, ticks and chewing lice

COMPANY: LoradoChem, Inc. Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, PA 18104-2891

CONTACT: Iain Weatherston, Ph.D., Technology Sciences Group, Inc., 4061 North 156th Drive, Goodyear, AZ 85338. Tel: 623-535-4060, Fax: 623-535-4061 and e-mail: iazkatz@qwestoffice.net.

PRODUCT: LC-2010-2 Fipronil for Dogs (File Symbol 86230 -E)

Dear Mr. Gebken:

As agent for, and on behalf of LoradoChem, Inc., I am submitting for your review and approval this PRIA Category R300 application to register LC-2010-2 Fipronil for Dogs, an insecticide to control fleas, ticks and chewing lice.

In addition to this letter, this one volume contains:

- Application for pesticide registration, EPA Form 8570-1
- Citation with respect to data citation, EPA Form 8570-34
- Formulator's exemption, EPA Form 8570-27
- Data Matrix, EPA Form 8570-35
- Child resistant packaging certification
- Letter of Authorization for LoradoChem, Inc. to submit and cite CRP data
- Draft label (five copies) one bound in this volume and four loose
- Confidential statement of formula.

In addition to this administrative volume, you will find additional data volumes included to satisfy product chemistry as well as child resistant packaging requirements.

Richard, this is the first of four applications for fipronil and fipronil plus S-methoprene containing products which will be submitted within the next 10 days. The last time I submitted multiple applications (not to you) the file symbols got messed up, and so this time and I hope that it does not cause any issues, I have assigned the file symbols as follows. I have also included the name and the EPA registration number of the "pioneer" product for which we are requesting an expedited review because of the "identical or substantially similar nature" of the new products.

LC-2010-1 Fipronil for Cats 86230-R identical/substantially similar to Frontline Top Spot for Cats (65331-2)

2 significant
error (e.g.)
see pg 2
of this ltr

LC-2010-2 Fipronil for Dogs 86230-E identical/substantially similar to Frontline Top Spot for Dogs (65331-2) **65331-3?**

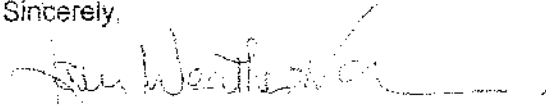
LC-2010-3 Fipronil and S-Methoprene for Cats 86230-G identical/substantially similar to Frontline Plus for Cats (65331-4)

LC-2010-4 Fipronil and S-Methoprene for Dogs 86230-U identical/substantially similar to Frontline Plus for Dogs (65331-5)

Also, I would ask you to note that the CRP data recently submitted for the cat mono product (Fipronil alone) is also applicable to the smallest iteration of the dog mono product i.e. for use on dogs less than 22 lbs. and will not be resubmitted with the dog application.

Should you required further information or have any questions, please do not hesitate to contact me by phone or e-mail.

Sincerely,



Iain Weatherston

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

LoradoChem, Inc.
Cira Centre, 12th Floor, 2929 Arch Street
Philadelphia, PA 18104-2891

REGULATORY ACTION:

Submission of the application to register LC-2010-2 Fipronil for Dogs (EPA File Symbol: 86230-E).

TRANSMITTAL DATE:


March 5, 2010

LIST OF SUBMITTED STUDIES:

MRID NUMBER	VOLUME NUMBER	EPA STUDY TITLE	GUIDELINE NUMBER
	1 of 8	LC-2010-2 Fipronil for Dogs Administrative Materials Volume 86230-E-1	-----
48013001	2 of 8	LC-2010-2 Fipronil for Dogs Product Chemistry Volume 86230-E-2	830.1550 – 830.1800 830.6000-7000
48013002	3 of 8	LC-2010-2 Fipronil for Dogs Child Resistant Packaging Testing Senior Panel Volume 86230-E-3 Study No.: GLM 10058	Non-guideline
48013003	4 of 8	LC-2010-2 Fipronil for Dogs Child Resistant Packaging Testing Senior Panel Volume 86230-E-4 Study No.: GLM 10053	Non-guideline
48013004	5 of 8	LC-2010-2 Fipronil for Dogs Child Resistant Packaging Testing Senior Panel Volume 86230-E-5 Study No.: GLM 10057	Non-guideline
48013005	6 of 8	LC-2010-2 Fipronil for Dogs Child Resistant Packaging Testing Child Panel Volume 86230-E-6 Study No.: GLM 29090	Non-guideline

48013006	7 of 8	LC-2010-2 Fipronil for Dogs Child Resistant Packaging Testing Child Panel Volume 86230-E-7 Study No.: 29092	Non-guideline
48013007	8 of 8	LC-2010-2 Fipronil for Dogs Child Resistant Packaging Testing Child Panel Volume 86230-E-8 Study No.: 10050	Non-guideline

COMPANY NAME: LoradoChem, Inc.

COMPANY OFFICIAL: 
Iain Weatherston, Senior Regulatory Consultant

COMPANY CONTACT: Iain Weatherston, Senior Regulatory Consultant
Technology Sciences Group, Inc.
4061 N 156th Drive
Goodyear, AZ 85395
(623) 535-4060

LoradoChem, Inc.
March 5, 2010

Please read Instructions of Registration of Pesticides Before Filing.

Form Approved, OMB No. 2070-0060, 04-0000, Expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 86230-E	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) LC-2010-2 Fipronil for Dogs	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) LoradoChem, Inc. Cira Centre, 12th Floor, 29292 Arch Street Philadelphia, PA 19104-2891 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 65331-3 Product Name Frontline Top Spot for Dogs	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

PRIA Category R300 - New product, fast-track. Please confirm with Iain Weatherston at: jatzkatz@qwestoffice.net

PRIA Pre-payment: Pay.gov Tracking ID: 250FQDJ6; Agency Tracking ID: 74104780391.

Section - III

1. Material This Product Will Be Packaged in:				2. Type of Container	
Child Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt. mL	No. per container	If "Yes" Package wgt	No. per container
			1, 3, 6		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container mL		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Iain Weatherston, Technology Sciences Group, Inc.	Title Senior Regulatory Consultant	Telephone No. (Include Area Code) (623) 535-4063
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both, under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Senior Regulatory Consultant	
4. Typed Name Iain Weatherston	5. Date March 5, 2010	

Form Approved. OMB No. 2070-0060. Approval Expires 5-31-98.



Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address LoradoChem, Inc. Cira Centre, 12th Floor 29292 Arch Street Philadelphia, PA 19104-2891	EPA File Symbol/Registration Number 86230-E
	Product Name LC-2010-2 Fipronil for Dogs
	Date of Confidential Statement of Formula (EPA Form 8570-4) March 5, 2010

As an authorized representative of the applicant for registration of the product identified above, I certify that:

- (1) This product contains the following active ingredient(s):**

Fipronil

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

- (3) Indicate by checking (A) or (B) below which paragraph applies:

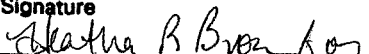
- ☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).


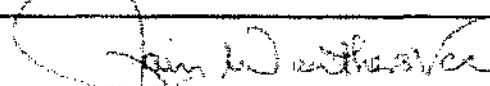
OR

- ☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

- (4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Fipronil		
Signature 	Name and Title Iain Weatherston, Senior Regulatory Consultant	Date March 5, 2010

 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460		
<p>Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPEE, Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.</p> <p>Do not send the completed form to this address.</p>		
Certification with Respect to Citation of Data		
Applicant/Registrant's Name, Address, and Telephone Number LoradoChem, Inc., Can Centro, 12th Floor, 29252 Arch St., Philadelphia, PA 19104-2891		EPA Registration Number/EPA Symbol 99139-1E
Active ingredient(s) and/or representative test compound(s) Fipronil		Date March 5, 2010
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Insect		Product Name LC-2010-2 Fipronil for Dogs
<p>NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 6570-27).</p>		
<input type="checkbox"/> I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).		
SECTION I: METHOD OF DATA SUPPORT (Check one method only)		
<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).		<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
SECTION II: GENERAL OFFER TO PAY		
[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]		
<input checked="" type="checkbox"/> I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required by FIFRA.		
SECTION III: CERTIFICATION		
<p>I certify that this application for registration, the form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.</p> <p>I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.</p> <p>I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.</p> <p>I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.</p> <p>I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.</p>		
Signature 	Date 3/5/2010	Typed or Printed Name and Title John Weatherston, Senior Regulatory Consultant



Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The Public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPP Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date March 5, 2010			EPA Reg. No./File Symbol 86230-E		Page 1 of 3
Applicant's/Registrant Name and Address LoradoChem, Inc. Cira Centre, 12 th Floor, 29292 Arch Street Philadelphia, PA 19104-2891			Product <i>LC-2010-2 Fipronil for Dogs</i>		
Ingredient Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.1550	Product Identity and Composition	This submission	LoradoChem, Inc.	OWN	
OPPTS 830.1600	Description of Starting Materials	This submission	LoradoChem, Inc.	OWN	
OPPTS 830.1650	Description of the Formulation Process	This submission	LoradoChem, Inc.	OWN	
OPPTS 830.1670	Discussion of the Formation of Impurities	This submission	LoradoChem, Inc.	OWN	
OPPTS 830.1750	Certified Limits	This submission	LoradoChem, Inc.	OWN	See CSF
OPPTS 830.1800	Enforcement Analytical Method	This submission	LoradoChem, Inc.	OWN	
OPPTS 830.6302	Color	This submission	LoradoChem, Inc.	OWN	
OPPTS 830.6303	Physical State	This submission	LoradoChem, Inc.	OWN	
OPPTS 830.6304	Odor	This submission	LoradoChem, Inc.	OWN	
OPPTS 830.6313	Stability (High Temperature etc)	This submission	LoradoChem, Inc.	OWN	
OPPTS 830.6314	Oxidation/Reducing Action	This submission	LoradoChem, Inc.	OWN	
Signature <i>Iain Weatherston</i>			Name and Title Iain Weatherston, Senior Regulatory Consultant		Date March 5, 2010

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version

Agency Internal Use Copy

612
LoradoChem, Inc.
March 5, 2010
Registration of LC-2010-2, Fipronil for Dogs

Page 12 of 37



Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The Public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, CPP Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date March 5, 2010		EPA Reg. No./File Symbol 86230-E		Page 2 of 3	
Applicant's/Registrant Name and Address LoradoChem, Inc. Cira Centre, 12 th Floor, 29292 Arch Street Philadelphia, PA 19104-2891		Product LC-2010-2 Fipronil for Dogs			
Ingredient Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.6315	Flammability	This submission	LoradoChem, Inc.	OWN	
OPPTS 830.6316	Explosibility	This submission	LoradoChem, Inc.	OWN	
OPPTS 830.6317	Storage Stability	This submission	LoradoChem, Inc.	OWN	
OPPTS 830.6319	Miscibility	This submission	LoradoChem, Inc.	OWN	
OPPTS 830.6320	Corrosion Characteristics	This submission	LoradoChem, Inc.	OWN	
OPPTS 830.6321	Dielectric Breakdown Voltage	This submission	LoradoChem, Inc.	OWN	
OPPTS 830.7000	pH	This submission	LoradoChem, Inc.	OWN	
OPPTS 830.7100	Viscosity	This submission	LoradoChem, Inc.	OWN	
OPPTS 830.7300	Density, Specific Gravity	This submission	LoradoChem, Inc.	OWN	
Non-Guideline	Child Resistant Packaging - Child Panel	This submission	LoradoChem, Inc.	PER	
Non-Guideline	Child Resistant Packaging - Senior Panel	This submission	LoradoChem, Inc.	PER	
Non-Guideline	Child Resistant Packaging - Child Panel	This submission	LoradoChem, Inc.	PER	
Non-Guideline	Child Resistant Packaging - Senior Panel	This submission	LoradoChem, Inc.	PER	
Non-Guideline	Child Resistant Packaging - Child Panel	This submission	LoradoChem, Inc.	PER	
Non-Guideline	Child Resistant Packaging - Senior Panel	This submission	LoradoChem, Inc.	PER	
Signature <i>Iain Weatherston</i>			Name and Title Iain Weatherston, Senior Regulatory Consultant		Date March 5, 2010

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version

Agency Internal Use Copy

022
LoradoChem, Inc.
March 5, 2010
Registration of LC-2010-2 Fipronil for Dogs

Page 13 of 37



Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The Public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPP Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date March 5, 2010		EPA Reg. No./File Symbol 86230-E		Page 3 of 3	
Applicant's/Registrant Name and Address LoradoChem, Inc. Cira Centre, 12 th Floor, 29292 Arch Street Philadelphia, PA 19104-2891		Product LC-2010-2 Fipronil for Dogs			
Ingredient Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
TOXICITY					
OPPTS 870.7200	Companion Animal Safety	"CITE-ALL"	See attached data submitters list	PAY	
OPPTS 870.1100	Acute Oral Toxicity	"CITE-ALL"	See attached data submitters list	PAY	
OPPTS 870.1200	Acute Dermal Toxicity	"CITE-ALL"	See attached data submitters list	PAY	
OPPTS 870.1300	Acute Inhalation Toxicity	"CITE-ALL"	See attached data submitters list	PAY	
OPPTS 870.2400	Primary Eye Irritation	"CITE-ALL"	See attached data submitters list	PAY	
OPPTS 870.2500	Primary Skin Irritation	"CITE-ALL"	See attached data submitters list	PAY	
OPPTS 870.2600	Skin Sensitization	"CITE-ALL"	See attached data submitters list	PAY	
PRODUCT PERFORMANCE					
OPPTS 810.3300	Treatments to Control Pests of Humans and Pets	"CITE-ALL"	See attached data submitters list	PAY	
Signature <i>Iain Weatherston</i>		Name and Title Iain Weatherston, Senior Regulatory Consultant		Date March 5, 2010	

EPA Form 3570-35 (9-97) Electronic and Paper versions available. Submit only Paper version

Agency Internal Use Copy

122
LoradoChem, Inc.
March 5, 2010
Registration of LC-2010-2: Fipronil for Dogs

Page 14 of 37

By Active Chemical Code -Sep 30, 2009 Edition

Company # Company Address

75234 AGRICULTURAL HANDLERS EXPOSURE TASK FO
PO BOX 509
MACON, MO 63557

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

CHEMICAL CHEMICAL NAME

129116 Benzoic acid, 3-chloro-2-[(5-ethoxy-7-fluoro(1,2,4)-

Company # Company Address

209 PNC CORP. AGRICULTURAL PRODUCTS GROUP
ATTN: MICHAEL C. ZUCKER
1735 MARKET ST, RM 1978
PHILADELPHIA, PA 19103

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			Y

Company # Company Address

62719 DOW AGROSCIENCES LLC
9330 VISIONVILLE RD 308/2E
INDIANAPOLIS, IN 46268

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
		Y				Y			Y

Company # Company Address

66607 SPRAY DRIFT TASK FORCE
MCKENNA, LONG & ALDRIDGE LLP
1900 K STREET, NW
WASHINGTON, DC 20006

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

71754 OUTDOOR RESIDENTIAL EXPOSURE TASK FORCE
1350 I STREET, N.W.
WASHINGTON, DC 20005

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

71755 AGRICULTURAL REENTRY TASK FORCE
1350 I STREET, N.W.
WASHINGTON, DC 20005

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

73989 PETER ENDANGERED SPECIES TASK FORCE, L
C/O HAROLD HIMMELMAN (BEVERIDGE & DIAMOND,
1350 I STREET, NW
WASHINGTON, DC 20005

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

CHEMICAL CHEMICAL NAME

129121 Fipronil

By Active Chemical Code -Sep 30, 2009 Edition

Company # Company Address

100 SYNGENTA CROP PROTECTION, INC.
ATTN: REGULATORY AFFAIRS
PO BOX 18303
GREENSBORO, NC 27419

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y									

Company # Company Address

264 BAYER CROPSCIENCE LP
2 T.W. ALEXANDER DRIVE
RESEARCH TRIANGLE PARK, NC 27709

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y		Y		Y	Y	Y			Y

Company # Company Address

432 BAYER ENVIRONMENTAL SCIENCE
A BUSINESS GROUP OF BAYER CROPSCIENCE LP
PO BOX 12014
RESEARCH TRIANGLE PARK, NC 27709

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y	Y						Y		Y

Company # Company Address

3282 ROCKWELL BENCKISER INC.
MORRIS CORPORATE CENTER IV
399 INTERPACH PARKWAY
PARLIPPANY, NJ 07054

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y						Y			Y

Company # Company Address

7946 J. J. MAUGET CO.
12733 DIRECTOR'S LOOP
WOODBRIE, VA 22192

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y									

Company # Company Address

7969 BASF CORPORATION
AGRICULTURAL PRODUCTS
PO BOX 13528
RESEARCH TRIANGLE PARK, NC 27709

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y	Y				Y		Y	Y	Y

Company # Company Address

9688 CHEMSTCO
DIV OF UNITED INDUSTRIES CORP
PO BOX 142642
ST LOUIS, MO 63114

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y									

Company # Company Address

53883 CONTROL SOLUTIONS, INC.
5903 GENOA-RED BLUFF
PASADENA, TX 77507

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
							Y		

Company # Company Address

54022 VIKRAC
PO BOX 16598
FORT WORTH, TX 76162

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y						Y			

Data Types									
------------	--	--	--	--	--	--	--	--	--

By Active Chemical Code -Sep 30, 2009 Edition

Company # Company Address

64240 COMBAT INSECT CONTROL SYSTEMS
C/O HENKEL CONSUMER GOODS INC.
122 C STREET, N.W., SUITE 740
WASHINGTON, DC 20001

EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y						Y			

Company # Company Address

65331 MERRILL LIMITED
3239 SATELLITE BLVD, BLDG 500, LOC 106B
DULUTH, GA 30096

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y	Y		Y			Y			Y

Company # Company Address

66607 SPRAY DRIFT TASK FORCE
MCKENNA, LONG & ALDRIDGE LLP
1900 K STREET, NW
WASHINGTON, DC 20006

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

71754 OUTDOOR RESIDENTIAL EXPOSURE TASK FORCE
1350 I STREET, N.W.
WASHINGTON, DC 20005

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

71755 AGRICULTURAL REENTRY TASK FORCE
1350 I STREET, N.W.
WASHINGTON, DC 20005

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

73342 AMBRANDS
118 1/2 EAST MAIN STREET, SUITE 1
SALEM, VA 24153

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y									

Company # Company Address

73766 INNOVATIVE PEST CONTROL PRODUCTS
PO BOX 880216
BOCA RATON, FL 33488

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y						Y			Y

Company # Company Address

73929 FIFRA ENDANGERED SPECIES TASK FORCE, D.
C/O HAROLD HIMMELMAN (BEVERIDGE & DIAMOND,
1350 I STREET, NW
WASHINGTON, DC 20005

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

74286 RESIDENTIAL EXPOSURE JOINT VENTURE (RE
900 17TH STREET, NW, SUITE 300
WASHINGTON, DC 20006

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

75234 AGRICULTURAL HANDLERS EXPOSURE TASK FO
PO BOX 509
MACON, MO 63552

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

By Active Chemical Code -Sep 30, 2009 Edition

Company # Company Address

69554 B2E CORPORATION
1501 EAST WOODFIELD ROAD, SUITE 200 WEST
SCHAUMBURG, IL 60173

EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

73989 FIFRA ENDANGERED SPECIES TASK FORCE, I
C/O HAROLD HIMMELMAN (BEVERIDGE & DIAMOND,
1350 I STREET, NW
WASHINGTON, DC 20005

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

74886 RESIDENTIAL EXPOSURE JOINT VENTURE (RE
900 17TH STREET, NW, SUITE 300
WASHINGTON, DC 20006

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

81390 ACTINIC INC.
7210 CESSNA DRIVE
GREENSBORO, NC 27409

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			Y

CHEMICAL CHEMICAL NAME

105402 S-Methoprene

Company # Company Address

1157 ADM ALLIANCE NUTRITION, INC.
1000 NORTH 30TH STREET, BOX C1
QUINCY, IL 62305

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

2517 SERGEANT'S PET CARE PRODUCTS, INC.
2625 SOUTH 156TH PLAZA
OMAHA, NE 68130

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y						Y			Y

Company # Company Address

2596 THE HARTZ MOUNTAIN CORP.
ATTN: ROBERT ROSENWASSER
400 PLAZA DRIVE
SECAUCUS, NJ 07094

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y							Y		Y

Company # Company Address

2724 WELLMARK INTERNATIONAL
1501 E. WOODFIELD ROAD, SUITE 200 WEST
SCHAUMBURG, IL 60173

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y						Y	Y		Y

By Active Chemical Code -Sep 30, 2009 Edition

Company # Company Address

43586 CHATEM, INC.
ATTN: DAVID SCHILLING, MGR REGULATORY AFF/
1715 WEST 35TH ST
CHATTANOOGA, TN 37405

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y									

Company # Company Address

43849 HNEORCOR PRODUCTS
A DIVISION OF ACUTY SPECIALTY PRODUCTS OF
1420 SEABOARD INDUSTRIAL BOULEVARD
ATLANTA, GA 30318

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

53883 CONTROL SOLUTIONS, INC.
5953 GUNOA-RED BLUFF
PASADENA, TX 77507

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

63823 MANAGEMENT CONTRACT SERVICES, INC.
PO BOX 5209
VALDOSTA, GA 31603

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y						Y	Y		Y

Company # Company Address

65331 MERIAL LIMITED
3239 SATELLITE BLVD, BLDG 500, LOC 106B
DULUTH, GA 30096

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
	Y		Y						Y

Company # Company Address

66607 SPRAY DRIFT TASK FORCE
MCKENNA, LONG & ALDRIDGE LLP
1900 K STREET, NW
WASHINGTON, DC 20006

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

69554 BZE CORPORATION
1501 EAST WOODFIELD ROAD, SUITE 200 WEST
SCHAUMBURG, IL 60173

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			Y

Company # Company Address

70062 BARCLINA BIOENVIRONMENTAL CENTRE LTD
PO BOX 5126
VALDOSTA, GA 31603

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

72947 EGIS PHARMACEUTICALS PUBLIC LIMITED CO
1150 18TH STREET, N.W., SUITE 1000
WASHINGTON, DC 20036

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

73349 VALENT BIOSCIENCES CORPORATION
870 TECHNOLOGY WAY, SUITE 100
LIBERTYVILLE, IL 60048

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y						Y			Y

By Active Chemical Code -Sep 30, 2009 Edition

Company # Company Address

73342 AMBRANDS
118 1/2 EAST MAIN STREET, SUITE 1
SALEM, VA 24153

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

73510 MARKETQUEST INC.
118 1/2 E MAIN ST, SUITE 1
SALEM, VA 24153

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y									Y

Company # Company Address

74032 AMZO CORPORATION
3330 NOYAC ROAD, BUILDING D
SAG HARBOR, NY 11963

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
									Y

Company # Company Address

74888 RESIDENTIAL EXPOSURE JOINT VENTURE (RE
900 17TH STREET, NW, SUITE 300
WASHINGTON, DC 20006

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

75318 B2E BIOTECH LLC
1501 EAST WOODFIELD ROAD, SUITE 200 WEST
SCHAUMBURG, IL 60173

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y						Y	Y		

Company # Company Address

82122 ZOCOR INCORPORATED
1001 G STREET, N.W., SUITE 500 WEST
WASHINGTON, DC 20001

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

CHEMICAL CHEMICAL NAME

105403 Trypsin Modulating Oestatic Factor (TMOF)

Company # Company Address

74411 INSECT BIOTECHNOLOGY, INC.
PO BOX 2311
CHAPEL HILL, NC 27515

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
					Y	Y			Y

CHEMICAL CHEMICAL NAME

105501 Tebuthiuron



Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The Public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPP Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date March 5, 2010		EPA Reg. No./File Symbol 86230-E		Page 1 of 3	
Applicant's/Registrant Name and Address LoradoChem, Inc. Cira Centre, 12 th Floor, 29292 Arch Street Philadelphia, PA 19104-2891		Product LC-2010-2 Fipronil for Dogs			
Ingredient Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			LoradoChem, Inc.	OWN	
			LoradoChem, Inc.	OWN	
			LoradoChem, Inc.	OWN	
			LoradoChem, Inc.	OWN	
			LoradoChem, Inc.	OWN	See CSF
			LoradoChem, Inc.	OWN	
			LoradoChem, Inc.	OWN	
			LoradoChem, Inc.	OWN	
			LoradoChem, Inc.	OWN	
			LoradoChem, Inc.	OWN	
			LoradoChem, Inc.	OWN	
Jain Weatherston			Name and Title Jain Weatherston, Senior Regulatory Consultant		Date March 5, 2010

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version

Agency Internal Use Copy

LoradoChem, Inc.
March 5, 2010
Registration of LC-2010-2 Fipronil for Dogs

Page 21 of 37



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The Public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, CPP Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date March 5, 2010			EPA Reg. No./File Symbol 86230-E		Page 2 of 3
Applicant's/Registrant Name and Address LoradoChem, Inc. Cira Centre, 12 th Floor, 29292 Arch Street Philadelphia, PA 19104-2891			Product LC-2010-2 Fipronil for Dogs		
Ingredient Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			LoradoChem, Inc.	OWN	
			LoradoChem, Inc.	OWN	
			LoradoChem, Inc.	OWN	
			LoradoChem, Inc.	OWN	
			LoradoChem, Inc.	OWN	
			LoradoChem, Inc.	OWN	
			LoradoChem, Inc.	OWN	
			LoradoChem, Inc.	OWN	
			LoradoChem, Inc.	OWN	
			LoradoChem, Inc.	OWN	
			LoradoChem, Inc.	PER	
			LoradoChem, Inc.	PER	
			LoradoChem, Inc.	PER	
			LoradoChem, Inc.	PER	
			LoradoChem, Inc.	PER	
			LoradoChem, Inc.	PER	
Signature Iain Weatherston			Name and Title Iain Weatherston, Senior Regulatory Consultant		Date March 5, 2010



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The Public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPP Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

[illegible]

LoradoChem Inc.
November 30, 2010
Registration of LC-2010-2; Fipronil for Dogs

Page 3 of 3

Confidential Statement of Formula may be entitled to confidential treatment

Confidential Statement of Formula may be entitled to confidential treatment